The open science model: its benefits and limitations in the framework of synthetic biology and the iGEM competition

Team Pasteur 2016

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Introduction

The interest for an open sharing of the scientific knowledge, or "open science", has shown a steady rise since the emergence of the Information Society, and the dazzling growth of the International Genetically Engineered Machine (iGEM) competition is a case in point. Created in 2003 as an independent study course at the Massachusetts Institute of Technology (MIT)[1], the iGEM has since expanded to become the largest worldwide synthetic biology (which can be described as "*the design and construction of new biological parts, devices and* systems" and "*the re-design of existing natural biological systems for useful purposes*"[2]) competition, gathering more than 300 teams for its 2016 edition[3]. The iGEM competition is ran by the iGEM Foundation, one of the broader goals of which is to promote the open and transparent development of tools for engineering biology[4], and thus to create an "*open community and collaboration*"[5].

The idea of openness in scientific research first emerged with the foundation of scientific Academies, and the publication of journals in the seventeenth century western countries. Before this period, the dominant ethos was one of aristocratic patronage, a system in which scientific research was financed by patrons for their sole prestige and/or entertainment[6]. But from a certain moment, scientists were not consistently funded by patrons anymore, and because a certain expectation around

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[1] http://igem.org/About, *About*, the iGEM website, last accessed 9 October 2016

[2] http://syntheticbiology.org/FAQ.html, *What is synthetic biology?*, syntheticbiology.org, last accessed 9 October 2016

[3] http://igem.org/Team_List.cgi?year=2016, *Team List For iGEM 2016 Championship*, the iGEM website, last accessed 9 October 2016

[4] https://en.wikipedia.org/wiki/International_Genetically_Engineered_Machine#Growth_and_recent_years, *International Genetically Engineered Machine*, Wikipedia, the free encyclopedia, last accessed 9 October 2016

[5] http://igem.org/About, *About*, the iGEM website, last accessed 9 October 2016

[6] Paul. A. David, *Understanding the emergence of « open science » institutions: Functionalist economics in historical context*, Industrial and Corporate Change, Oxford Journals, 2004, 13 (4): 571-589

science was growing among the society, national academies started to appear (namely the Royal Society in England in 1660, and the French Academy of Sciences in France in 1666), followed by academic journals devoted to science[7][8]. Much later, with the creation of the Internet and the means of mass communication, the issue of opening the scientific process has become all the more important. Nevertheless, it is still far from being solved, namely because open science appears to go up against all of the "traditional" intellectual property rights, which provide their holder with an exclusive right to exploit their intangible property.

The purpose of this report is to study ***the benefits and limitations of the open science model, in the framework of synthetic biology and the iGEM competition****.*

In view of what is aforementioned, this work will be divided into three parts. It will first concentrate on defining and giving the core principles of the open science system (**I**). Then in a second time, the functioning of the iGEM competition will be dissected and analyzed (**II**). Lastly, efforts will be made to conciliate the rules that will be developed as part of this study with the pursuit of iGEM projects, in a private or open framework (**III**).

I - Definition and core principles of the open science system

A. Meaning and History of Open Science

1) Attempted definition

The open science movement was born out of the realization that although science in some ways appears to have a strong collaborative aspect, nowadays its practice tends to be kept personal. Indeed, methods, data and preliminary results

[7] Ibid.

[8] James E. McCellan III, *Science Reorganized: Scientific Societies in the Eighteenth Century*, New York: Columbia University Press, 1985

are often detained until publication, if they ever get published. But because the issues that arise with the advance of science are logically getting harder to address, it has become clear that some problems that might never be addressed by isolated researchers would require scientists to join forces in order to be solved.

It is difficult to give a precise definition of open science, mainly because while the concept is actually quite ancient, it has only started to be analyzed recently. Although open science encompasses other issues related to openness, J. Daniel Gezelter, Professor of Chemistry, University of Notre Dame warns that "*one must not fall back on a litany of "Open source, Open Data, Open Access, Open Notebook*" to define it[9]. Open source refers to "*something people can modify and share because its design is publicly accessible*"[10], and Open Data is "*data that anyone can access, use or share*"[11]. As to Open Access and Open Notebook, the first means "*making peer reviewed scholarly manuscripts freely available via the Internet*", while the latter throws back to "*the practice of making* [an] *entire project available online as it is recorded*", which in a way is the "*online analog to the paper notebook most scientists keep in their lab*"[12].

According to Librarian Michael Peper, "***transparency, across the entire practice of science, is what defines Open Science***. (…) *Instead of limiting the sharing of the practice of science to publication of selected results, the entire scientific process should be exposed to potential users, collaborators and extenders of the work*"[13]. In 2011, writer, scientist and programmer Michael Nielsen posted an "informal"

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[9] http://www.openscience.org/blog/?p=269, J. Daniel Gezelter, *What, exactly, is Open Science?*, The OpenScience Project, July 28, 2009

[10] https://opensource.com/resources/what-open-source, *What is Open Source?*, opensource.com, last accessed 26 September 2016

[11] https://theodi.org/what-is-open-data, *What is open data?*, Open Data Institute, last accessed 26 September 2016

[12] http://blog.scienceexchange.com/2012/06/open-notebook-series-what-is-an-open-notebook/, Anthony Salvagno, *Open Notebook Series: What is an Open Notebook?*, the Science Exchange blog, June 22 2012, las accessed 26 September 2016

[13] http://blogs.library.duke.edu/scholcomm/2010/09/13/what-is-open-science/, Michael Peper, *What is Open Science ?*, Scholarly Communications @ Duke, Duke University Libraries, September 13, 2010

definition of open science over at the open-science mailing list at okfn.org[14]: "***Open science is the idea that scientific knowledge of all kinds should be openly shared as early as is practical in the discovery process***"[15]. Multiple other definitions can be found by browsing sites such as Science Commons[16], or The OpenScience Project[17], but in any case, as M. Peper rightly points out, the spirit is always that there should be **transparency to the methods, observations, data collection, data access, communication, collaboration and research tools**[18]. Prof. J. D. Gezelter specifies that when working on science that involves numerical experiments, granting access to source code is equivalent to publishing the methodology[19].

Aside from attempting to properly define open science, open community members have laid down different set of aims and principles to help understand the concept. **Prof. J. D. Gezelter argues that open science has four essential objectives**[20]:

- Transparency in experimental methodology, observation, and collection of data;
- Public availability and reusability of scientific data;
- Public accessibility and transparency of scientific communication;
- Using web-based tools to facilitate scientific collaboration.

Similarly, **four principles were presented by the Science Commons website**[21] at the "Policy and Technology for e-Science" workshop, that was organized by the EuroScience[22] association in 2008[23]:

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[14] Open Knowledge International (OKFN) is a "*worldwide non-profit network of people passionate about openness, using advocacy, technology and training to unlock information and enable people to work with it to create and share knowledge*" (https://okfn.org/about/)

[15] https://lists.okfn.org/mailman/listinfo/open-science, *Open Science – Discussion List for the Open Science Community*, Open Knowledge Foundation

[16] https://creativecommons.org/about/program-areas/open-science/, *Open Science*, Creative Commons (previously Science Commons)

[17] http://www.openscience.org/blog/, *The Open Science Project*

[18] Michael Peper, op. cit.

[19] http://www.openscience.org/blog/?p=269, J. Daniel Gezelter, *What, exactly, is Open Science?*, The OpenScience Project, July 28, 2009

[20] Ibid.

- Open Access to Literature from Funded research;
- Access to Research tools from Funded research;
- Data from funded Research in the Public Domain;
- Invest in Open Cyberinfrastructure.

After having attempted to determine what was referred to as "open science", the study will quite logically focus on defining the movement's historical background.

2) A History of the Open Science movement

The open science movement is actually much more ancient than one may think. Indeed, it emerged during the late sixteenth and early seventeenth, and was part of the Scientific Revolution, prior to which science as the pursuit of Nature's Secret was subject to secrecy. Before this period however, virtually all of the conditions inveighed against openness in the scientific approach.

In his reference essay on the historical origins of open science, academic economist Paul A. David provides a very accurate picture of the scientific state of mind on disclosure of new knowledge, according to the times and society[24].

In classical Greece for instance, science was essentially developed in the framework of competitive public debate between different schools of thought, which inhibited collaboration among scientists by setting them against each other.

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[21] http://sciencecommons.org/resources/readingroom/principles-for-open-science/, *Principles for open science*, Science Commons, 2008

[22] http://www.euroscience.org/, *EurosScience*

[23] http://sciencecommons.org/events/esof-satellite-event/, *Policy and Technology for e-Science*, Science Commons

[24] http://www-siepr.stanford.edu/workp/swp06008.pdf, Paul A. David, *The Historical Origins of "Open Science", An Essay on Patronage, Reputation and Common Agency Contracting in the Scientific Revolution*, Stanford University & The University of Oxford, June 2007

In the Middle Ages, political and religious authorities prevented the disclosure of the Secrets of Nature to the "vulgar multitude". In his aforesaid study, Prof. David takes the example of the *Kitab Sirr al-Asrar* ("The Book of the Secret of Secrets"). While the "*most popular book in the middle ages*" (to use the wording of historian of medieval science and alchemy Lynn Thorndike[25]) was supposedly spreading the knowledge of Aristotle, it promulgated the idea that said knowledge was to be kept secret from the "unworthy". P. David adds, for another illustration, that goddess Natura was generally portrayed as being hostile to an open disclosure of her secrets. In any case, being refractory to the Secrets of Nature was "*a conviction woven into the very fabric of medieval thought*"[26].

In the Renaissance, the general attitude towards a full disclosure of scientific discoveries was still pretty tepid, and "*philosophers skillfully hid magic behind secret words, and this they did for altruistic motives*"[27], what is particularly evidenced by the adage *si haec scientia homnibus esset discoperta, confunerent universum* ("if this knowledge was revealed to all men, it would confound the universe").

Moreover, as Prof. David notes, the imperative of secrecy was particularly developed in the philosophical and protoscientific **tradition of alchemy**, which was regarded as a "divine" and "personal" science. Natural philosopher, chemist and physicist Robert Boyle inferred from the alchemists' "*obscure, ambiguous, and almost enigmatical way of expressing what they pretend to teach, that they have no mind to be understood at all, but by the sons of the art*"[28].

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[25] Lynn Jr. Thorndike, *History of Magic and Experimental Science, Vol. 2 (Second Edition)*, New York: Columbia University Press, 1950/1958.

[26] William Eamon, *From the Secrets of Nature to Public Knowledge: The Origins of the Concept of Openness in Science*, Minerva, 23 (3), 1985, pp. 321-347

[27] Paolo Rossi, *Hidden Knowledge, Public Knowledge*, Ginevra Sintesi: manuscript, May 2005

[28] Robert Boyle, *The Sceptical Chymist: or Chymico-Physical Doubts & Paradoxes*, J. Cadwell, 1661

The institutions that first promoted openness in science really arose with **the Enlightenment**, the period in which the western thought and culture went through a series of upheavals in science, philosophy, society and politics. At this moment, as Professor and Director of the Garwood Center for Open Innovation[29] Henry Chesbrough explains, "*there was something of a Cambrian explosion in scientific institutions, as the pursuit of knowledge migrated from royal patrons to a much larger bourgeoisie. This migration caused a tremendous increase in both the volume of scientific knowledge generated, and in the speed with which new discoveries diffused within society*"[30]. According to Prof. Chesbrough, the landmark events were the **formations of the national science societies**, starting in 1660 with the **Royal Society**, which published its **Philosophical Transactions of the Royal Society** as of 1665 (other societies were soon created in France, Berlin, Russia and Sweden). H. Chesbrough points out that "*by 1700, there were over 30 scientific journals being published, which would skyrocket to more than 1,000 journals a century later*".

It was also during this period that the norms of science came to be established. Sociologist Robert K. Merton noted in his *Sociology Of Science* that these norms of behavior "*cumulatively contributed significantly to the growth and quality of scientific knowledge*"[31], and attempted to package them into an outline he termed **CUDOS**:

- **"Communalism** – sharing discoveries with others, in which scientists give up intellectual property in exchange for social recognition gained through sharing;
- **Universalism** – claims to truth are evaluated in terms of universal criteria, and should be reproducible by others under the same conditions

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[29] http://corporateinnovation.berkeley.edu/, *Garwood Center for Corporate Innovation*, Haas School of Business, University of California Berkeley

[30] http://www.sciencebusiness.net/eventsarchive/OpenScience/OpenScience.pdf, Henry Chesbrough, *From Open Science to Open Innovation*, Science Business Publishing, 2015, p. 5

[31] Robert K. Merton, *The Sociology of Science: Theoretical and Empirical Investigations*, University of Chicago Press, 1973

- **Disinterestedness –** the researcher's attitude is one of objectivity; such that the researcher follows the evidence wherever it goes, regardless of its implications for profit or lack of profit;
- **Originality –** research results should yield novel contributions to understanding;
- **Skepticism –** all ideas are subject to rigorous, structured community scrutiny, which curates the quality of the work that results"[32].

Following this trend of greater transparency in the making of science came an opposite tendency with the **birth and development of "traditional" Intellectual Property Law** in the western world, which would lead to the pre-eminence of "*commercially oriented R&D based upon proprietary information*"[33]. The owners of legal monopoly became free to impose high access charges for data, information and research tools, which, as emphasized by P. David, had adverse effects, namely because it would "*encourage public research institutes to "valorize" their results by patenting,* (…) *organize a private commercial exploitation, and to promote the exclusive licensing by research universities of patent, awarded to those institutions on the basis of discoveries and inventions arising from the publicly funded work of their faculties*"[34]. Furthermore, firms that have a monopoly will understandably have weaker incentives to invest in developing inventions and introduce product innovation with equivalent companies on a competitive market.

But the aforementioned "Mertorian" norms have found expression in new institutions with the **emergence of the Internet** and the move towards an **information society** as known today. Indeed, improved cyber infrastructures generate knowledge that spreads at a speed and on a scale that were previously unthinkable.

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[32] Ibid.
[33] Paul A. David, op. cit., p. 1
[34] Ibid.

Prof. J. D. Gezelter relates how in 1998, open science seemed to him as a "*pretty obvious projection of basic scientific principles into the digital age*", which he didn't think would "*meet much, if any, resistance from the scientific community*". But then, as he points out, making cultural changes in the scientific community is found to be an incredibly time-consuming process[35].

The end of the nineties was the period when the **term "open science" came into use**, and when initiatives seeking to promote open science have started to be introduced by private and public entities alike.

To cite a few American examples, in October 1999, Brookhaven National Laboratory[36] sponsored the "Open Source / Open Science" meeting, which Prof. J. D. Gezelter describes as a "*pretty utopian gathering*"[37], and in June 2013, the OSTP[38] celebrated the Champions of Change for Open Science at the White House (an event in which Prof. J. D. Gezelter also took part and which he described on the OpenScience Project website)[39]. In the same year, Mozilla, the producer of the Firefox browser, also launched its own open science initiative called "Mozilla Science Lab"[40].

As regards Europe, the signs of a global shift towards openness in science are mainly seen from the strategy of the European Union (EU), which aims at "*making research findings available free of charge for readers*" in order to "*improve*

[35] http://www.openscience.org/blog/?p=686, J. Daniel Gezelter, *OpenScience Comes of Age*, TheOpenScience Project, June 23, 2013

[36] https://www.bnl.gov/world/, *Brookhaven National Laboratory*

[37] J. Daniel Gezelter, op. cit.

[38] The Office of Science and Technology Policy (OSTP) was established by the Congress in 1976 with a broad mandate "*to advise the President and others within the Executive Office of the President on the effects of science and technology on domestic and international affairs*" (https://www.whitehouse.gov/administration/eop/ostp/about)

[39] https://www.whitehouse.gov/champions/open-science – at this occasion, 13 individuals and organizations were honored for sharing their science.

[40] https://science.mozilla.org/, *Mozilla Science Lab*

knowledge circulation and thus innovation"[41]. This change momentum ties in closely with Horizon 2020, the "*biggest EU Research and Innovation programme ever with nearly €80 billions of funding available over 7 years (2014 to 2020)*"[42]. Within the Horizon 2020 programme is the "Science with and for Society" section, which has, as one of its objectives, to "*allow all societal actors* (…) *to work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of European society*". This approach is called "Responsible Research and Innovation" (RRI)[43].

As this historical overview goes on to demonstrate, the open science movement has gradually developed to become a major societal and even political issue. To conclude this first part of the study, a few open science experiments will now be described to serve as illustrations.

3) Concrete Open Science applications

Editor and staff writer at Priceonomics[44] Alex Mayyasi relates the story of the effort that was made in 2003 to bring nonprofits, academia, and the private sector together to collaborate on Alzheimer's research[45]. This initiative was referred to by the New York Times as the "***Alzheimer's Disease Neuroimaging Initiative***" (ADNI)[46]. The purpose of this public-private project was, among other things, to "*share all the*

[41] https://ec.europa.eu/programmes/horizon2020/en/h2020-section/open-science-open-access, *Open Science (Open Access)*, Horizon 2020, The EU Framework Programme for Research and Innovation
[42] https://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020, *What is Horizon 2020?*, Horizon 2020, The EU Framework Programme for Research and Innovation
[43] https://ec.europa.eu/programmes/horizon2020/en/h2020-section/science-and-society, *Science with and for Society*, Horizon 2020, The EU Framework Programme for Research and Innovation
[44] https://priceonomics.com/, *Priceonomics*
[45] https://priceonomics.com/open-science-vs-intellectual-property/, Alex Mayyasi, *Open Science vs Intellectual Property*, Priceonomics, May 21 2013
[46] http://www.nytimes.com/2010/08/13/health/research/13alzheimer.html?pagewanted=all&_r=0, Gina Kolata, *Sharing of Data Leads to Progress on Alzheimer's*, The New York Times, August 12 2010

data [from the project], *making every single finding public immediately, available to anyone with a computer anywhere in the world*". As the New York Times details, no one could own the data, nor be entitled to submit patent applications, but the major interest for private companies lied in the profit they could ultimately gain from any drugs or imaging tests that would be developed as a result of the effort[47]. Organizations and companies that were involved in the ADNI raised over $94 million, worked with 800 test subjects over many years, created a common public data set, and published publicly available papers, which would have been prohibitively expensive and risky otherwise[48]. Alzheimer's researcher at the University of Pennsylvania Dr. John Q. Trojanowski thought it was *"unbelievable"*. "*We all realized that we would never get biomarkers unless all of us parked our egos and intellectual property noses outside the door and agreed that all of our data would be public immediately*"[49].

Another enlightening example is given by business administration professor Karim R. Lakhani in a 2006 interview for the HBS Working Knowledge website[50]. In said interview, Prof. Lakhani shares the story of an internal science team at a major biotechnology firm which was assigned to develop a method for rapid and simple detection of DNA sequences in unconventional field settings. After several months of trying to get the method, the team came to the conclusion that no viable solution existed for their problem. But because solving it was considered as an imperative, the firm decided to disclose the specifics of the problem to external scientists and to request a solution in return for substantial prize money.

> "*In a four-week period of time, over 574 scientists investigated the problem statement and forty-two of them submitted potential solutions for*

[47] Ibid.
[48] Alex Mayyasi, op. cit.
[49] Gina Kolata, op. cit.
[50] http://hbswk.hbs.edu/, *Working Knowledge*, Harvard Business School

considerations. The winning solution was proposed by a scientist from Finland who did not work in this field. The solution involved the novel application of an existing methodology to the problem at hand. Besides solving the problem, the solution information opened up a new knowledge domain for future investigations and resulted in a valuable patent for the firm."[51]

Plenty of other examples can be found to show that open science is a promising way of overcoming difficulties inherent to the traditional practice of science, such as the Open Science Grid[52], the Research Data Alliance[53], or the FoldIt[54] biology program. It seems in any case that the movement of open science is leading to an era of "*citizen science*", or "*crowdscience*", to use H. Chesbrough's wording, "*where important scientific contributions can be made by ordinary people from all over the world*"[55].

[51] http://hbswk.hbs.edu/item/open-source-science-a-new-model-for-innovation, Martha Lagace, *Open Source Science: A New Model for Innovation*, Working Knowledge, Harvard Business School, November 20 2006

[52] The Open Science Grid (OSG) "*facilitates access to distributed high throughput computing for research in the US*" (https://www.opensciencegrid.org/)

[53] https://rd-alliance.org/, the Research Data Alliance (RDA) is an initiative for "*sharing the source data collected in the scientific process, so that research data and research methods that lead to new science can also be shared*" (Henry Chesbrough, op. cit., p. 6).

[54] https://fold.it/portal/, FoldIt is enlisting ordinary contributors to solve complex protein folding problems.

[55] Henry Chesbrough, op. cit., p. 6

B. Critics and benefits of the open science system[56]

Since its earliest stages in the sixteenth century, the open science movement has raised numerous criticisms, which have evolved over time. Currently, this movement is facing three main objections. Firstly, even though the open science movement has been rejuvenating in the early 90's with technological advances, it is still facing challenges, due to the intrinsic nature of the science community and the drawbacks resulting from opening data to society. Therefore, it seems that a relevant solution to accommodate defenders of open science with practical difficulties would be to elaborate a compromise license-based regime.

1. A contextual resurgence of the open science movement, facing structural impediments

As described above, the open science movement was in certain decline with the development of patents and the intellectual property system, but it started regaining some ground in the early 90's. This resurgence is driven by several factors.

a. The globalization of the scientific community and the raise of digital technologies…

The exchange of ideas and people across the world has increased substantially over the last two decades due to several circumstances: the emergence of east Asia as

[56] Even though this section of the report will attempt to expose the arguments of both parties in a clear and non-subjective way, the reader needs to keep in mind that the advocates of open science tend to communicate much more openly on their position than its critics, and they also tend – for understandable reasons – to make their work more accessible. Therefore, there might be a wider variety of sources in favor of the open science movement which shall not imply that open science advocates constitute a wider group than its critics.

one of the greatest economic powers[57], the increased international mobility of students[58] and researchers, and the development of technologies in the 90's, making the access to information – and especially scientific data – always easier.

b. … creating the ideal context for the development of open science.

Within this context, international institutions (namely, the European Commission), have decided to stimulate the open science movement. In its Horizon 2020 Framework Programme for research and innovation (R&I) (2014-2020), the European Commission estimates that the current situation is pushing towards the opening of scientific data. The Commission wishes to develop "science with and for society" and has set the following goal: "The aim is to build effective cooperation between science and society, to recruit new talent for science and to pair scientific excellence with social awareness and responsibility". Open science would, according to the Commission, enable society to respond to the "increasing demand to address societal challenges of our time". In its recommendations, the Commission is pushing very strongly in favor of the opening of research data, and prescribes explicit measures to achieve that end, such as "Opening research organizations in the European research area". The agenda of the Commission contains the following elements: adopt best practices for reward and evaluation systems, alternative models for open access publishing ; management of research data and reuse of research data, developments of standards, fostering research integrity, developing citizen science [59].

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[57] National Research Council (US) *Committee on Policy Implications of International Graduate Students and Postdoctoral Scholars in the United States.* Washington (DC): National Academies Press (US); 2005.

[58] Todd M. Davis. 2003. *Atlas of Student Mobility*. New York: Institute of International Education.

[59] Council of the European Union, *The transition towards an Open Science system*, 27 May 2016.

Having the support of international institutions is a strong argument for those in favor of open science, since the ideas of the Commission – sometimes ahead of their time – often become implemented in national legislations.

2. Critics within the scientific community, keeping the open science regime from blooming

But even with such a strong support from European institutions, the scientific community is still very reluctant to switch from the traditional system to an open science system for several reasons.

The growing ease to communicate research data among the scientific community and to the public is one of the main pro-open science arguments, but it's detractors put forward the fact that too much unsorted data could have a counterproductive effect, and overwhelm scientists. It could indeed slow down the research process, by making scientists analyze a much larger quantity of data than necessary to conduct their research. Although, this counterproductive effect could be minimized by following an efficient information-sorting process.

But a major hindrance to the development of this movement, is the inner working of the scientific community. For centuries (since the appearance of the patent and the whole intellectual property system), scientists have been encouraged to work in a closed environment. Indeed, the current reward system is based on three components: money, reputation, and time, resources and space[60]. By "giving away" the product of their research, scientists would renounce to their publication priority,

[60] J. Daniel Gezelter, *OpenScience comes of age*, The OpenScience Project, June 23, 2013

which is crucial to their H-indice, their reputation, and their career in general. The whole research incentive system is simply not built to accommodate open science, mostly because of the competition for publication.

3. A raising voice in favor of open science, struggling to overcome its limitations

a. Among software developers

A growing number of scientists and researchers fully support open science for a vast number of reasons. For instance, Martha Lagace, PhD in social anthropology[61] at Boston university and Karim R. Lakhani, an assistant professor at Harvard Business School[62] support the idea that in the open source software community is particularly suitable to "large-scale scientific problem solving"[63]. Indeed, the open source philosophy is most popular among the software scientific community, this is mainly because software developers are more concerned about problem-solving, than researchers in "pure sciences" who focus their efforts on publication.

But even if there is clear evidence of the success of open science projects among software developers, other domains of science could highly benefit from it. Indeed, for any numerical experiment, if the researcher is not being granted access to the source code of the programs that they use to conduct experiments, the outcome of their experiment will completely depend on the coding abilities of the developer[64].

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[61] (PAS SUR QUE CETTE NOTE RESTE) and former senior editor in "Working knowledge", an online journal edited by Harvard Business School.

[62] (CELLE-LA NON PLUS) with an extensive research background in open source software communities and their innovation and product development strategies.

[63] Martha Lagace, 'Open Source Science: A New Model for Innovation' [2006] 1(1) Working Knowledge, The Thinking That Leads by Harvard Business School.

[64] J. Daniel Gezelter, *OpenScience comes of age*, The OpenScience Project, June 23, 2013.

Nevertheless, open science detractors could argue that this success is mostly due to its limitation to the software community and these principles couldn't apply to other domains of science, because of a different inner functioning. For example, according to Maryann E. Martone, professor in the Department of Neurosciences at the University of California, "in the Open Source Software community, (…) identifying and fixing a bug is considered a compliment, in other areas of scholarship, it is considered an attack"[65]. This is only one of the many differences creating a gap between the software community and the rest of the scientific community, where the success of scientists relies almost exclusively with publication frequency and quality.

Regardless, granting access the source code of a program to its users can indeed prevent biased results, but this is mostly applicable to numerical experiments, and is more difficult to transpose to experimental domains of science, that rely more on practical experiments than theoretical machine-originated results.

b. Among the rest of the scientific community

Even though developers are the strongest advocates of an open science regime, a voice has started to raise among other scientists to encourage their peers to share their data and experiment results. But again, their ideal is facing strong limitations, inherent to the functioning of the scientific community, both in the private and public domains.

Maybe the strongest argument in favor of the development of open science, is the fact that "one problem may reside in one domain of expertise, and the solution may

[65] Maryann Martone, 'Open Science? Try Good Science' [2014] Wiley Exchanges - Discover the future of research.

reside in another"[66]. In "The Value of Openness in Scientific Problem Solving", Karim R. Lakhani, Lars Bo Jeppesen, Peter A. Lohse & Jill A. Panetta have conducted an experiment where they asked twenty-six firms and scientific laboratories to open up a set of one hundred and twenty-six scientific problems to the whole community. The outcome of their experiment was that one-third of the problems were resolved by independent scientists who were complete outsiders to the problem, because they approached the problem that was submitted to them with a new mindset. Indeed, submitting a problem to an expert of a different field will allow it to be considered in a new perspective, where the solution may lie.

Using the same pattern, the Innocentive initiative[67] connects organizations facing a roadblock with volunteer "solvers" from around the world that will provide them with solutions answering their problem. This platform is meeting a great success but is still facing criticisms that can be addressed to the open science philosophy in a whole.
Firstly, the solutions submitted by solvers on the Innocentive platform remain private. Only the organization that had submitted the problem (and the platform) can access the solution. This functioning may seem odd considering the website's approach towards open science, but is in fact very understandable. Indeed, revealing the solution to the rest of the community might give away a lot on the firm's strategy. Private firms especially are very secretive of their solutions, which is only right in a competitive market, where they need to keep their technological advance. Some firms are even reluctant to disclose the issues that they are facing, because the problems they encounter can give out a lot on their strategy. Furthermore, some big enough firms might host a sufficient variety of skills to apply

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[66] Lakhani, K. R., Jeppesen, L. B., Lohse, P. A., & Panetta, J. A. (2007). *The value of openess in scientific problem solving* (pp. 07-50). Division of Research, Harvard Business School.

[67] https://www.innocentive.com/about-us/

this kind of method without disclosing any element of their strategy to outside researchers, and therefore endanger their intellectual property.

Pr. Lakhani partially rejects this argument by claiming that even if a firm reveals their problems and gives out part of their solution, a potential competitor could have difficulties implementing that same solution in another setting. According to him, "knowledge is sticky", and even if some results are published, they imply a lot of tacit knowledge to be reproduced that is not easily transferred[68].

Now, regarding public researchers, who are not bound by market competitiveness, disclosing problems or solutions might give too much information on the current state of their research, which would disadvantage them in the race for publication.

Although, if we consider the situation in a whole, scientists would highly benefit from the opening of their research data to the rest of the community, in the sense that a growing privatization of data and information impedes the opportunity for the scientific community to annotate and document existing results and sources of information, "necessary to maintain reliably accurate and up-to-date public database resources [degrading] the effectiveness of the research system as a whole"[69].

Even though this is a very valid point, one could consider that researchers already comment on build on each other's work in a very effective manner, allowing research to progress every day. On the other hand, the opening of data and results to the general public could be harmful for several reasons.

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[68] Lakhani, K. R., Jeppesen, L. B., Lohse, P. A., & Panetta, J. A. (2007). *The value of openess in scientific problem solving* (pp. 07-50). Division of Research, Harvard Business School.

[69] Stanford Institute For Economic Policy Research SIEPR; Discussion Paper No. 06-38;

THE HISTORICAL ORIGINS OF 'OPEN SCIENCE' An Essay on Patronage, Reputation and Common Agency Contracting in the Scientific Revolution By Paul A. David; Stanford University & the University of Oxford; December 2007.

4. Limitations of the Open Science system

Firstly, increasing the mass of data, experiments and comments, without a qualitative filter (such as publication in a renowned journal) could lead to a decrease in the quality of the publications and comments, and would make the conduct of any kind of research more fastidious, since scientists will have to process a larger quantity of material. If open science becomes the norm, publications will have to be sorted out very efficiently by topic and by quality, in order not to overwhelm researchers with a mass of data of lesser value. What's more, increasing the scale of published scientific results will make their verification more difficult, and therefore contribute to the deterioration of the publication's scientific quality.

Secondly, the general public is not able to understand and process complex scientific data. For instance, in "The New Era of Networked Science"[70] Michael Nielsen cites the example of the launch of the Kepler mission in 2009, which was supposed to be followed by release of collected data to the the public prior to their analysis by scientists, but finally decided against it, by fear of the data being misinterpreted by the grand public. NASA finally released the data after scientists had performed a thorough analysis and could address the public's comments.

These arguments demonstrate that even if circumventions can occur, the current science system, due to ideological and practical obstacles, is simply not ready to switch to an open science system. Although, we should not consider the situation in a binary "all open" or "all closed" way, and maybe the development of new licensing schemes would offer a satisfactory compromise.

[70] Nielsen, Michael (2011). Reinventing Discovery: The New Era of Networked Science. Princeton, N.J.: Princeton University Press. ISBN 978-0-691-14890-8.

5. The development of new licensing schemes: a promising solution

The issue about open science really are about incentive and sustainability. Sharing results is a very counterintuitive way of working for most scientists. The whole scientific reward system would have to be reshaped in order to encourage researchers to make their results available. In the current system, individual scientific productivity is quantified by the H-indice (that depends on the number of publications and the number of citations). But a scientist's career will mostly depend on these indicators. When it comes to companies, as we have seen before, they tend to be very secretive about the information they detain, in order not to compromise their intellectual property. According to Prof. J. D. Gezelter [71], the current system is flawed, and "research shouldn't be considered complete until the data and meta-data is put up on the web for other people to use". For him, we need to change our culture of science, and expect researchers to put their data online for peer review and reuse.

Therefore, a good compromise between society's best interest, and a stimulating and rewarding research environment for scientists that would also preserve companies immaterial added value could be to look for a solution in the licensing system. Licenses are a very powerful mean to share creations in a customizable way, granting and refusing the rights, depending on the license's aim and will be developed further.

This system, although very complete, would have to be adapted to embrace the variety of creations. Indeed, licenses are not (yet) suitable to protect actual inventions. Some groups of researchers are willing to address this situation by

[71] J. Daniel Gezelter, *OpenScience comes of age*, The OpenScience Project, June 23, 2013

creating an “hybrid patent”, that would behave more or less like a license, and would allow its right holder to tailor the rights he wishes to grant to each user (or group of users) individually, and some research groups have made very promising suggestions that will be discussed further.

C. The system of the licenses

6. What is a license?

A license is "a permit from an authority to own or use something" according to the Oxford Dictionary. Applied to intellectual property it means that the creator or the owner of the intellectual property rights, the "authority", **allows the licensee to use its work.** As for instance by giving the right to the beneficiary to use the creator's painting as an illustration or execute a patented invention without risk of infringement.

A license is a promise by the licensor not to sue the licensee: normally if someone uses a creation protected by intellectual property rights, the right holder can rest upon the legal system and attack him for infringement.

The licenses are really various in terms, territory, renewal provisions, modalities, types, for instance: A *franchise* (to give someone your name and savoir-faire), a *publication*, a *patent license* (for the use of an invention), a *brand license* (to let someone use your brand to sell his products), a *music license* (to authorize someone to broadcast your song), a *software license*, *artwork license* (to grant a permission to the user to copy and distribute a creation).

However, concerning open science, open data, open access and open source there are **specific licenses to frame the free exchange of works, data and knowledge**.

Historically the software and computer community created the open source licenses. These licenses give access to everyone to the source code of a software or a computer program and depending on the licenses, the user can freely run, study, modify, and redistribute the program commercially.

The **General Public License** (GPL) is one of the first free and open source license. It allows the user to run, study, share and modify the software. The only constraint is that the work itself or the work derived have to be **shared by the user under the same conditions as the GPL**, meaning free open access. This obligation of share-alike is what constitutes a **copyleft license.**

This copyleft license is opposed to the **most permissive free software licences** in the domain: the Berkeley Software Distribution (BSD) and the MIT licenses, which do not have a **share-alike condition.** Meaning that the user can modify the source code and not give an open access when he redistributes it, even commercially.

However the copyleft licenses are considered by most as essential to **keep a viable community**, to avoid that some software companies take the contributions of others programmers without giving back to the community.

7. The expansion of open access licenses to every field of knowledge: the case of Creative Commons

A lot of licenses were then developed for open access and open data, outside the world of computers and source code. These licenses can be free of charge or not, with many restrictions or completely permissive, they also can be revoked (but the revocation is not retroactive).

The most known and used licenses are the **Creative Commons licenses**[72]**.** Instead of sharing a source code of a software, it allows the **sharing of a work.**

The particularity of the Creative Commons is that the contributor can **choose among different conditions to build the license** the most adapted to his needs: the right to

[72] Creative Commons is a non-profit organization that has released several copyright-licenses known as Creative Commons licenses free of charge to the public.

adapt, modify, make a commercial use of the work, and share in the same conditions.

But for the six copyright licenses, there is a common and mandatory condition: **attribution**, the user must give appropriate credit to the creator.

The terms of the Creative Commons licenses are written to be **legally in compliance with international** intellectual property **treaties**, therefore applicable in all the signatory members of these treaties. Nevertheless, Creative Commons works to build localized versions of the licenses tailored to accommodate fine legal details of various countries and the terms and nuances in their language. These licenses and their localized versions bring more **legal certainty for the parties** and the interests at stake.

The Creative Commons helps to **legally frame the exchange of knowledge,** fostering innovation, creation development and equity. It is adapted to share music, movies, images but also various other contents. There is a **wide range of fields of application**: arts and culture, legal tools and licenses, policy and advocacy, open access, open science, education, open data and technology.

Platforms like flickr, Wikipedia, YouTube, internet archive, vimeo, skills commons, jamendo, PLOS publications[73] and many more use Creative Commons.

8. The difficulties of transposing this system into the world of science

[73] PLOS publications is a website and journal based on Open Access, that publishes articles in various scientific domains (*biology, medicine, genetics, pathogens, tropical diseases*) free to access, reuse and redistribute permitting transparency, strong peer review and faster innovation.
PLOS Public Library of Science, 2016. Who we are. [online] Available at <https://www.plos.org/who-we-are> [Accessed 20 September 2016]

Open science is growing in popularity, viewed as the base for fast innovation and equity. The Council of the European Union[74] in *The Transition towards an Open Science system* sets the goals for the Horizon 2020 Program.

One of the main components of this European Program is to « remove barriers and foster incentives », therefore it encourages scientists to **remove unnecessary legal barriers** by not using their copyright on their scientific works. Pushing them to explore other legal possibilities, the Council of the European Union even **advises scientists to use licenses** such as Creative Commons for scientific publications and research data sets.

Even if the goal is set, the public opinion moves slower. There are two main issues of transposing these types of licenses in the world of science: first, most of the existing licenses rely on a copyright regime and not on the patent legislation; second, open science comes into conflict with the deep thinking of a need of proprietary rights and patents among researchers and industries.

To understand the difference between aesthetic creations and technical inventions, the functioning of the system of intellectual property should be further explained.

In intellectual property, there are two main branches: **Copyright** and **Industrial Property**.

The first one refers more to artistic works: literary works, films, choreography, music but also computer programs and databases. Whereas industrial property refers more to commercial and industrial works: patents for inventions, trademarks, designs and models.

The main difference lies in the **registration**, for copyright no registration is needed

[74] The Council of the European Union, 2016. *Council conclusions on the transition towards an Open Science System*, 27 May 2016, RECH 208 TELECOM 100

to access protection while it is necessary to access the protection granted by the industrial property regime. Copyright protection is automatically granted to artistic works, simply as a result of the creation.

This registration for patents and other components of industrial property is expensive and time consuming, especially if the inventor seeks protection in many countries.

That is why there are domains where open science and the use of licenses are really developed: s**cientific publications and data sets**, partly because scientific publications and data sets rely on the **copyright regime** in most countries. For instance, the aforementioned PLOS publications that publishes scientific articles in open access relies on a Creative Commons license. Moreover open science can be a real springboard for the scientists' career: thanks to citations and media attention ("open publications get more citations"[75]), potential collaborations and job opportunities become numerous.

However, regarding patents, the impediments are numerous considering the difference between the two regimes.

First of all, as Dan L. Burk mentions[76], there is a sort of paradox between open source and the condition of disclosure in the patent legislation.

Indeed, one of the requirements to access patent protection is disclosure: the description must be detailed enough to allow a man of the art to make and use the invention. The functioning, method, data are accessible for everyone, so it could appear that it fulfils the spirit of open source movement.

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[75] Erin C McKieran, *Point of view : How open science helps researchers succeed*, eLife 2016 ;5:e16800, July 7, 2016 https://elifesciences.org/content/5/e16800

[76] Dan L. Burk, *Intellectual Property and Cyberinfrastructure*, Designing Cyberinstructure for Collaboration and Innovation – Special Issue, Volume 12, Number 6 – 4 june 2007

However, a patent gives an exclusive right to the owner to use it and to prevent others from using, distributing it. And in numerous jurisdictions in the world there are few and sometimes no exceptions to the monopoly of the inventor for research, experiment use or reverse engineering. This is strongly contradicting the spirit of open science.

There is therefore a sort of misunderstanding in the terms used (open source, open access), the terms cannot be interchangeable at the whim of the fields, as A. G. Gonzales points[77] and adding that "The heart of the movement is the distribution of intellectual works through permissive licenses". Indeed if a patent allows everyone to access and read the technology which can be seen as open access, the patent does not allow a free of charge, open distribution and use of the work therefore there is no real open access and open science.

Scientists are also more reluctant than artists and non-technical creators to share their work without restrictions because a patent is an economic reward to the scientist for the progress it brings to the society, the economic reward is to give an inventor a monopoly for the commercial use of the invention.

Yet if an open license is applied to a patented invention the reward is not ensured. The inventor will not own a monopoly, besides in certain sub licenses he can be forbidden to exploit its derived invention commercially. This is a major obstacle because the inventor has to pay the high price to access the protection of a patent, but under an open science license the commercial reward is not ensured.

Industrial Property being related more to commercial technologies; it raises also other difficulties for the application of licenses.

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[77] Andrés Guadamuz Gonzalez, *Open Science: Open source licenses in scientific research*, 2006, University of Edinburgh, p.15

First, it is more subject to competition law than copyright. A license could raise antitrust concerns not predicted in the terms.

Second, the corporate world is institutional, hierarchic and capitalist. A patent is often a goal for academic labs working under a research director, and mostly investors and enterprises want intellectual property rights to have a competitive advantage, to be able to bargain in the industry.

To address this issues, there are a lot of initiatives to build licenses adapted to open science for patented technologies.

4. The complex emergence of open science adapted licenses, like the BioBrick Public Agreement (BPA)

As a result of the lack of scientific adapted licenses, some rely on homemade licenses with often a copyleft style (a share-alike condition). Nevertheless, this practice of isolated homemade licenses can weaken the movement by making the landscape of open licenses really complex and confusing.

Some projects are on the rise such as the Biological Open Source (BiOS)[78] funded by CAMBIA, which developed new licensing on the base of "open source software movement" tailored for biological innovation.

> To "***enable the sharing of the capability to use patented and non-patented technology***, *which may include materials and methods, within a dynamically expanding group of those who all agree to the same principles of responsible sharing, a "protected commons"*[79].

The licensees must agree to legally binding conditions: the heart of the innovation should **not be appropriated** and there is a **share-alike condition** (improvements of

[78] http://www.bios.net/daisy/bios/home.html
[79] http://www.bios.net/daisy/bios/mta.html

the work must be shared). The licensee has then access to the scientific work, but also improvements, information and data of others licensees as well and can commercially exploit it.

Other initiatives can be underlined: Creative Commons is developing licenses adapted to the sharing of scientific data and also a new way of licensing patents under the project of Science Commons[80], Open Science License by Fabien Benureau[81] who wants to apply the Lesser General Public License (LGPL) to scientific code ensuring that the user will release the modifications under the same license.

The BioBrick Public Agreement (BPA) is another example of a free and open access license adapted to scientific technology and knowledge. Created by the BioBrick Foundation (Foundation close to the iGEM Competition), who considers that "Fundamental biotechnology belongs to all of us".

Thought in the spirit of free and open source programming computer language, the BPA wants to build a free and open source "language for programming life".

The BPA is a **legal tool** to allow the Contributor to give his **biological part for free to anyone who wants to use it.**

Concerning the terms of this exchange, the **Contributor** must complete the contributor agreement specifying what intellectual property right he has on the BioBrick (patent for instance) and **agrees to hold his intellectual property rights**, that is to say to not sue the user for infringement when he uses his BrioBrick. He also decides if he wants attribution or not.

In the other hand, the **User** must give attribution and work **ethically** with this biological part but he is **free to use any BioBrick**. Unlike certain open access licenses,

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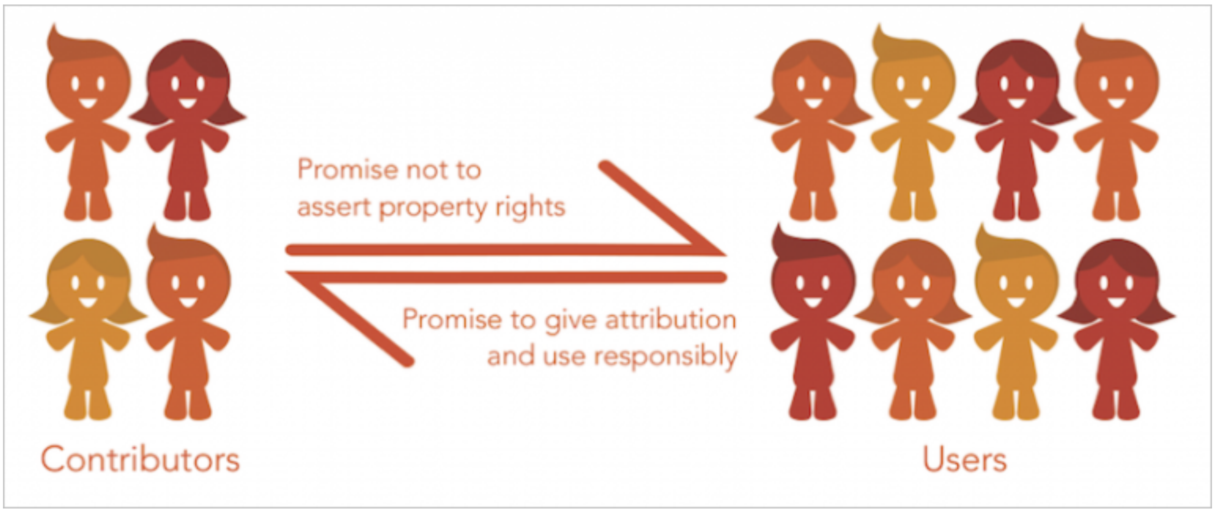
80 http://sciencecommons.org/about/

81 http://fabien.benureau.com/openscience.html

he does not have to give back any of his work and can eventually patent its derived work.



[82]

Another solution proposed by A. G. Gonzales and already used by certain public interest institutions or small research facilities that cannot afford a patent, is to release the technologies **into the public domain** (without any patent or licenses). This methods allows the free sharing of the work and to short-circuit similar patent applications, by making the research public which makes the mandatory condition of novelty null.

Open science licenses for patents and non-patented technologies face many issues: how to financially reward the scientists? Especially for high costs research and development technologies; how to avoid the stealing of the technology by non-open science industry?

Nevertheless, there is a strong need for a viable license in order that the movement of open science grows bigger, that is why the initiatives aforementioned should be encouraged and developed with maybe the help of legal international institutions.

[82] https://biobricks.org/sharingandinnovation/

II. The iGEM competition

A. The iGEM competition: basic rules and philosophy

1. iGEM: the first synthetic biology international competition

In order to define iGEM, one must at first explain what synthetic biology is. There are several definitions of synthetic biology, however, the SynBERC (Synthetic Biology Engineering Research Center) gives a very accurate one of this new science area: "Synthetic biology is a maturing scientific discipline that combines science and engineering in order to design and build novel biological functions and systems. This includes the design and construction of new biological parts, devices, and systems (e.g., tumor-seeking microbes for cancer treatment), as well as the re-design of existing, natural biological systems for useful purposes (e.g., photosynthetic systems to produce energy)"[83]. Alternatives definitions are given, by the High-level Expert Group European commission for instance, which describes synthetic biology as such: "Synthetic biology is the engineering of biology: the synthesis of complex, biologically based (or inspired) systems which display functions that do not exist in nature. This engineering perspective may be applied at all levels of the hierarchy of biological structures – from individual molecules to whole cells, tissues and organisms. In essence, synthetic biology will enable the design of 'biological systems' in a rational and systematic way."[84]

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[83] What is synthetic biology? [online] SynBERC [accessed on Sept. 12th 2016] https://www.synberc.org/what-is-synbio.

[84] Synthetic Biology Applying Engineering to Biology - Report of a NEST High-Level Expert Group – European Commission. Page 10.

Synthetic biology is a relatively new science field, and the iGEM competition played a significant role in its development by introducing undergraduate, overgraduate students and the general public to these new problematics.

iGEM stands for "International genetically engineered machine". It is the first international competition[85] in synthetic biology and it is hosted every year by the Massachusetts Institute of Technology (MIT) in October in Boston. IGEM started off as an MIT course in 2003 and grew exponentially over the past decade. It became a summer competition with five teams in 2004, and teams from outside the US started enrolled in the competition in 2005 (starting with the ETH Zurich team[86]). For the 2016 edition, there are more than 300 registered teams, coming from every continent of the world.

iGEM competitors gather into teams of approximately four to twenty students, and elaborate a synthetic biology project over the year (some teams compete once every two years to have more time to complete their project). The iGEM website gives the following description of how every project takes place, and this is also how the Pasteur Paris team organized in 2016: "*Timelines are different for every project; however, in general teams begin to organize between December and January. They need to get faculty approval, recruit members, fundraise, and brainstorm project ideas. Between the start of February and the end of March, the teams will register (which includes paying the registration fee, providing a resource description, and providing contact information so teams can receive important emails from iGEM HQ and their DNA Distribution Kits) and, once they are approved by iGEM Headquarters, they will receive their DNA Distribution Kit sometime in April.*

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[85] iGEM is comprised of more elements than just the competition which are going to be detailed further in this section. However, it is the most important part of the whole iGEM organization, and when the iGEM is mentioned, it is most often a reference to the competition.

[86] IGEM 2005 - Project Summaries [online] – 2006 igem [accessed on Sept. 12th 2016] http://2006.igem.org/wiki/index.php/IGEM_2005_-_Project_Summaries.

Once the kits arrive, work in the lab will take place between May - August. During these months, teams will get together in regional meetup events, work outside the lab doing community outreach activities, and will document their efforts in their wikis. At the end of the summer, the Giant Jamboree will bring all of the teams together to share and celebrate their hard work".

Students usually find iGEM to be an extremely positive and enriching experience, where they get the opportunity to autonomously set up a science project and present their creations in front of a jury composed of researchers[87].

When it comes to the protection of creations, the iGEM policy is very interesting, since the iGEM foundation has adopted the open science approach.

2. The iGEM philosophy and values

The iGEM values are explicitly detailed on the foundation's communication material as such : "integrity, good sportsmanship, respect, honesty, celebration, cooperation, effort, excellence"[88]. In an interview, Randy Rettberg, president of the iGEM

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[87] My iGEM impressions: by Marina Maletic

As soon as I heard about the iGEM competition, I knew I wanted to participate in it. I was lucky enough to join such an inspirational team in one of the most prestigious research facilities in France. Over the summer, I experienced the liberty and the joy of bringing to life an idea that was ours to begin with. What an amazing feeling it is to work in laughter and still see your experiments working! The thought of helping the society with our project is what kept us going like this for months. But most of all, I believe we became friends for life.

[88] iGEM – Values http://igem.org/Values

foundation, focuses and elaborates on four of these values and explains why they are so critical to iGEM.

According to him, the most essential of iGEM values is **effort**: everyone's hard work needs to be **celebrated** (the teams, the judges, and everyone participating in iGEM). "iGEM is not easy, iGEM is worth the effort"[89]. Indeed, many of the projects are worthy of startup companies, or would be great potential PhD thesis subjects.

Then comes the second value, which is "respect". It is critically important that all the teams behave with respect for other people involved, for technology, for the project, for the public.

Finally, a third crucial value according to Randy Rettberg is "**cooperation"**, because open source science is building. This is why the team's work needs to be published on the wiki, so that it can last and help following teams. Presentations are also videotaped and everything is available under the creative commons attribution 4.0 license, which is the most permissive license in the sense that it allows sharing and adaptation of the licensed material, the only prerequisite being that the user gives "appropriate credit, provide[s] a link to the license, and indicate[s] if changes were made"[90].

But with that sharing vision, it is essential that other contributors can trust the information they find online on the wikis, this is why **integrity** is another decisive iGEM value. Teams must, at all times, be concerned with the quality and integrity of

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accessed on Sept. 13th 2016

[89] Randy Rettberg in : iGEM – Values http://igem.org/Values accessed on Sept. 13th 2016

[90] Creative commons – attribution 4.0 international accessed on Sept. 13th 2016 https://creativecommons.org/licenses/by/4.0/

the material they publish, and they must not conceal wrong or incomplete results by using ambiguous wording.

When asked if a competition was the best way to embody all these values, Randy Rettberg replied that competitions were "a human mechanism for bringing focus", and critical for raising money. Therefore, iGEM founders are not the only ones to have selected this way of promoting synthetic biology, and other competitions in synthetic biology have seen the light of the day, sometimes embracing a different philosophy.

3. The iGEM vision compared to other synthetic biology competitions'

a. The CAGEN (Critical Assessment For Genetically Engineered Networks) competition

The path of open science chosen by the iGEM founders was not the only one possible. Other competitions in synthetic biology exist (on much smaller scales) such as CAGEN (Critical Assessment For Genetically Engineered Networks). The competition founders have decided to release their content under the Creative Commons Attribution-ShareAlike 3.0 Unported license, (or, at competitor's option, under the GNU Free documentation license version 1.2 or later)[91]. The first license mentioned is slightly more restrictive than the license creative commons attribution 4.0 chosen by iGEM founders, as it also allows sharing and adaptation of the material, but if the primary material has been remixed, transformed or built upon, the contributions must be distributed under the same license as the original[92]. The

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[91] OpenWetWare : copyrights – openwetware.org - accessed on Sept. 13th 2016 – page last modified on 7 may 2008
[92] Creative commons – attribution-sharealike 3.0 unported - accessed on Sept. 13th 2016 https://creativecommons.org/licenses/by-sa/3.0/

second license, free documentation license 1.2 is even slighter restrictive, as it allows copy and distribution of the licensed document but without changes[93].

These slight restrictions nevertheless do not negate the open science aspect of the CAGEN competition. The aim of the competition is still to "bring together leading research groups in biological circuit design to compete"[94].

b. The GenoCon competition

The international Rational Genome-Design Contest (GenoCon) is another competition in synthetic biology, launched by the Japanese RIKEN research institute in 2010. The aim of this competition is for contestants to make "effective use of genomic and protein data contained in SciNeS database clusters to design DNA sequences that improve plant physiology"[95]. As in iGEM, no real prize is offered to the contestants, but they get recognition for their work.

The main difference between iGEM and GenoCon is that participants in GenoCon are able to keep sequences they use secret "if they are negotiating joint patent or licensing agreements with other businesses"[96]. Tetsuro Toyoda, RIKEN Bioinformatics and Systems Engineering Division (BASE) Director, hopes that this option is going to encourage "small-scale business groups and university people

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[93] GNE Free documentation license – GNU operating system - accessed on Sept. 13th 2016 - http://www.gnu.org/licenses/fdl-1.3.en.html

[94] CAGEN - Overview of the competition – openwetware.org http://openwetware.org/wiki/CAGEN#More_information accessed on Sept. 13th 2016 – page modified on 23 May 2012

[95] GenoCon: An international science and technology competition supporting future specialists in rational genome design for Synthetic Biology – online – Riken.jp - http://www.riken.jp/en/pr/topics/2010/20100524/ - accessed on Sept. 14th 2016

[96] Synthetic-biology competition launches – online – Nature – accessed on Sept. 14th 2016. http://www.nature.com/news/2010/100602/full/news.2010.271.html

with patented DNA sequences to use [their] platform to find much more optimized versions of the sequences claimed in the patent. Tetsuro Toyoda calls this framework "open-optimization research".

In comparison with iGEM, Masayuki Yamamura[97], points out in an interview for Nature, that the iGEM's parts registry being open access discourages industrials to take interest in the competition.

c. Legal and ethical issues at stake in the competitions

- Intellectual property issues

Despite what M. Masayuki Yamamura was saying in the aforementioned interview, iGEM isn't disconnected at all from the industrial world. Indeed, there are many examples of past iGEM projects that have turned into successful businesses. For instance, the UC Davis 2013 Entrepreneurship team has built on their iGEM project to launch a company called AmberCycle (in the renewable products industry)[98]. The MIT-Entrepreneurship 2012 has also turned their project "Benchling" into a company that provides an online service to help editing, analyzing and sharing DNA sequences[99].

But, we need to acknowledge that, even though it is possible, it is harder to build on an open science project and turn it into a profit-making company, because of legal

[97] PhD, Professor at the Tokyo Institute of Technology, School of computing MASAYUKI YAMAMURA Researcher Information- online – Tokyo Tech research repository - http://t2r2.star.titech.ac.jp/cgi-bin/researcherinfo.cgi?lv=en&q_researcher_content_number=CTT100381356 - accessed on Sept. 14th 2016.

[98] Vision – Ambercycle Industries – Online – accessed on Sept 19th 2016 - http://2012e.igem.org/Team:UC_Davis_E/Vision

[99] Homepage – Benchling – Online – accessed on Sept 19th 2016 - http://2012e.igem.org/Team:MIT_E

issues, and more specifically concerning synthetic biology, patenting issues. This will be further developed in the report, but in brief, taking part into the iGEM competition prevents iGEM teams to register a patent on the submitted biobricks, (and more broadly, to protect through intellectual property everything that has been submitted) that now belong to the open science community. Without being incompatible with the development of a for-profit structure, this policy can be perceived by some as a drag on the development of a company.

- Environmental and public health issues

Besides the intellectual property issues arising from the competition, iGEM also raises legal and ethical questions more directly related to synthetic biology. This field in science is indeed quite new, and even though the immense potential of this promising subject, it is still subject to very serious legal restrictions. Indeed, we do not know yet the long term effects of modifying genomes, and on the grounds of prudence, the release of synthetically engineered material is extremely regulated.[100] For instance, member states are responsible for taking the appropriate measures to avoid every negative effect that the release of GMOs could have on the environment or human health[101], and every release of GMO in the environment must be priory notified to the Member State where the release is to take place[102].

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[100] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration « PART A GENERAL PROVISIONS Article 1 Objective

In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when: - carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community »

[101] Article 4

General obligations

In the framework of many iGEM projects, these legal provisions need to be taken into account, because in the eventuality of the projects being carried on further after the competition, the competitors will have to comply to these rules. For instance, between 2008 and 2014, 117 projects aimed at using synthetic biology to clean polluted water[103], such as the Munich 2013's project : physco filter. Their project relied on "transgenic plants which produce effectors for enzymatic degradation (BioDegradation) or specific binding (BioAccumulation)"[104] these plants would have acted as a water filter, and a kill-switch[105] would have prevented unintended bacteria dissemination in the environment by limiting viability to places where the spectrum of sunlight is appropriately filtered.

Besides environmental bacteria spreading, there is a major public health issue with some of the iGEM projects, mainly the ones competing within the "diagnostics" and "therapeutics" tracks (previously gathered under the name "health and medicine").

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1. Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs.

[102] Article 6

Standard authorisation procedure

1. Without prejudice to Article 5, any person must, before undertaking a deliberate release of a GMO or of a combination of GMOs, submit a notification to the competent authority of the Member State within whose territory the release is to take place.

[103] Team seeker – "clean water" online – accessed on September 20th 2016 - http://igem-qsf.github.io/iGEM-Team-Seeker/dist/

[104] Physco filter – home page - http://2013.igem.org/Team:TU-Munich

[105] To prevent genetically modified bacteria from escaping into the wider environment, researchers have developed safeguards in the form of two so-called "kill switches," which they call "Deadman" and "Passcode." These kill switches can cause synthetic bacteria to die without the presence of certain chemicals. MIT news – MIT - http://news.mit.edu/2015/kill-switches-shut-down-engineered-bacteria-1211

Indeed, these projects aim at creating medical solutions using synthetic biology, which would sometimes put the targeted population in direct contact with genetically modified organisms or infectious material. For instance, the 2016 iGEM Pasteur projects aims at detecting which arboviruses can be found in a given geographical area. For this purpose, the project is divided into a two-phase system, including vector capture and analysis. During the capture phase, a mosquito trap is placed in the environment. Therefore, at a certain stage in the process, a trap filled with potentially infectious mosquitoes will be left unattended in the environment. In order for the project to be viable, the team had to come up with a solution to avoid the possibility of contact between the population and the potentially infectious material[106].

- How these issues are being addressed in the framework of the iGEM competition and more broadly, in research in synthetic biology

These are only a few examples of how iGEM projects could have implications on society, and why these issues need to be addressed by iGEM competitors, and more broadly by researchers who enable synthetic biology to progress.

However, iGEM competitors are not left alone with the responsibility of elaborating projects complying with safety regulations. Indeed, some institutes around the world focus their research on "Responsible Research and Innovation" (RRI). RRI is "an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation"[107].

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[106] Mosquito – a biosilica based detection device – online accessed on 22nd September - http://2016.igem.org/Team:Pasteur_Paris

[107] HORIZON 2020 - The EU Framework Programme for Research and Innovation – European commission – online - accessed on 22nd September -

RRI has become a real guideline for scientific institutions, private and public, and is being fostered by the European Commission in the Horizon 2020 program. European institutions want to raise awareness in the scientific community on the necessity to implement RRI in the whole research process. This translates into the first title of the EU Framework Programme for Research and Innovation: "Institutional Change to Support Responsible Research and Innovation in Research Performing and Funding Organisations". This title is backed up by a list of provisions that define how this objective should be achieved such as:

- "Reviewing their own procedures and practices in order to identify possible RRI barriers and opportunities at organisation level;
- Creating experimental spaces to engage civil society actors in the research process as sources of knowledge and partners in innovation;
- Developing and implementing strategies and guidelines for the acknowledgment and promotion of RRI;
- Adapting curricula and developing trainings to foster awareness, know-how, expertise and competence of RRI;
- Including RRI criteria in the evaluation and assessment of research staff"[108].

Some organizations and institutes are here to help research institutions to implement these guidelines. For instance, the Rathenau Instituut in the Netherlands "promotes the formation of political and public opinion on science and technology. To this end, the Institute studies the organization and development of science systems, publishes about social impact of new technologies, and organizes debates

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https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation

108 HORIZON 2020 - The EU Framework Programme for Research and Innovation – European commission – online - accessed on 22nd September - https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation page 9

on issues and dilemmas in science and technology"[109]. This kind of institutions collaborates strongly to the development of RRI and guides scientists towards a safe research path. They also play the essential intermediate role between researchers and the general public, by helping researchers take into account the social and ethical aspect of their research, and by introducing society to complex scientific issues.

[109] Rathenau instituut – about us – online - accessed on 22nd September - https://www.rathenau.nl/en/about-us

B. BioBricks, Wiki and Jamboree: The iGEM Ecosystem

1) BioBricks

The iGEM competition mostly amounts to the making and handling of standardized biological parts called "**BioBricks**", which were proposed by synthetic biologist and computer engineer at MIT Tom Knight in 2003 as a standard for physical composition of biological parts[110]. Those are "***interchangeable parts, developed with a view to building biological systems in living cells***"[111], which fall into eight types: Ribosome Binding Sites, Regulatory, RNA, DNA, Protein Coding, Terminators, Conjugation, and BioScaffold[112]. The major interest of the BioBricks resides in their ability to be pieced together to build complex biological devices: this process is often referred to as "**Standard Assembly**".

The word "biobrick" is actually a trademark owned by the BioBricks Foundation (BBF)[113], a public benefit organization created in 2006 by engineers and scientists alike to democratize the use of standardized biological parts in the research area. Because the BBF is dedicated to "*advancing synthetic biology to benefit all people and the planet*" and because it claims that "*fundamental biotechnology belongs to all of us*"[114], the possession of such title may appear to run counter to the Foundation's ideals. To defend itself against this apparent discrepancy, the BBF argues in the frequently asked questions of its website that the holding of a

[110] http://dspace.mit.edu/bitstream/handle/1721.1/21168/biobricks.pdf?sequence=1, Tom Knight, *Idempotent Vector Design for Standard Assembly of BioBricks*, Tech. rep., MIT Synthetic Biology Working Group Technical Reports, 2003, last accessed 23 September 2016

[111] http://parts.igem.org/Help:An_Introduction_to_BioBricks, *Help: An Introduction to BioBricks*, The iGEM Registry of Standard Biological Parts, last accessed 22 September 2016

[112] http://parts.igem.org/Part_Types, *Part Types*, The iGEM Registry of Standard Biological Parts, last accessed 22 September 2016

[113] http://biobricks.org/, *BioBricks Foundation*, last accessed 22 September 2016

[114] https://biobricks.org/donate/, *biobricks/SUPPORT*, BioBricks Foundation, last accessed 22 September 2016

trademark on uses of the word "*biobrick*" is to "*protect its free-to-use and open technical standards and legal framework*", further emphasizing that "*as a government recognized public-benefic organization the BBF has no intention of profiting from these public-benefic services*"[115].

2) The iGEM Wiki

To make the iGEM teams' accomplishments comparable between each other, their entire projects have to be documented on the iGEM wiki, in which they are given a personal space that they can freely organize until the "Wiki Freeze" deadline. For the 2016 edition of the competition, the wikis are as follows: 2016.igem.org/Team:Team_Name.
It is explicitly stated on the wiki requirements page of the iGEM website that "***all content*" must be hosted by teams on their wiki**, that is all "*pages, images, documents and codes*": in sum, teams shall not link to any element that would be hosted on other servers (nor can they use iframes).

But from a legal standpoint, the most important indication, which can be found at the bottom of the wiki requirements page, is that all content on the iGEM wiki falls under a **Creative Commons License**[116].
Creative Commons is a non-profit organization whose purpose is to build up a legal framework for making creative works available online. By pursuing this goal, the organization hopes it will allow the sharing of "*knowledge and creativity to build a more equitable, accessible, and innovative word*", and thus that it will "*unlock the*

[115] https://biobricks.org/bpa/faq/, *Frequently Asked Questions*, BioBricks Foundation, last accessed 22 September 2016
[116] http://2016.igem.org/Requirements/Wiki, *Requirements/Wiki*, the iGEM 2016 website, last accessed 24 September 2016

full potential of the internet to drive a new era of development, growth and productivity"[117].

To take on this role, Creative Commons provides **six free copyright licenses** that are **customizable** based on the preferences, and automatically generated through the use of an online form[118]. In practical terms, the licensee is allowed to **precisely encompass an authorized perimeter of sharing or distributing of their copyrighted content without prejudice to their right to ownership**.

All six different Creative Commons Licenses (CC) have three important features in common:

- They ensure **proper attribution**, so that "*licensors get credit for the work they deserve*"[119];
- They are valid **throughout the world**;
- They **last until the copyright expires**, because they are built upon it;

Creating a CC generates a frame that contains icons indicating the chosen license preferences. Following are the five main icons:

(cc) To express that the content falls under a **Creative Commons** License

(BY) To express that **attribution** must be given in the manner specified by the licensor

(NC) To express that any **commercial use of the work is forbidden**

(SA) To express that sharing adaptations of the work is allowed as long as others **share alike**

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[117] https://creativecommons.org/about/, *What we do – What is Creative Commons?*, Creative Commons, last accessed 24 September 2016

[118] https://creativecommons.org/choose/?lang=en, *Choose a License*, Creative Commons, last accessed 24 September 2016

[119] https://creativecommons.org/licenses/?lang=en, *About the Licenses – What our Licenses do*, Creative Commons, last accessed 24 September 2016

(ND) To express that **sharing adaptations of the work is forbidden**

Icons by The Noun Project

What the iGEM uses for the teams' wikis is the **Creative Commons Attribution License 4.0** (or any later version), whose symbol is pictured below:

Icon by The Noun Project

As can be seen, the iGEM has chosen the most permissive Creative Commons License possible, allowing users to **freely share altered copies** of works, **even for commercial purposes**. In return, users of contents sourced from the iGEM wiki are given a single imperative: they have to **give attribution**, which means "*give appropriate credit, provide a link to the license, and indicate if changes were made*"[120]. It should however be stressed that the users' range of action remains circumscribed by the fact that Creative Commons Licenses do not concern patents, trademarks, or any other industrial property right.

3) The Giant Jamboree

After a whole summer of hard work on their project, the teams from all around the world finally meet for the "**Giant Jamboree**". This annual five-day event is a global showcase of the teams' accomplishments that takes place at the Hynes Convention Center, in Boston. The Jamboree is mainly about the teams presenting their projects through both **poster sessions** and an **oral presentation**, but it also includes networking sessions, social events, talks, workshops, discussion forums, and more[121].

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[120] https://creativecommons.org/licenses/by/4.0/, *Attribution 4.0 International (CC BY 4.0)*, Creative Commons, last accessed 25 September 2016

[121] http://2016.igem.org/Giant_Jamboree/Schedule, *Schedule*, the iGEM 2016 website, last accessed 25 September 2016

The Jamboree is undoubtedly a critical part of the iGEM competition, because it is at this occasion that the teams compete to **gain medals and awards**. The projects are grouped into fourteen different categories called "**tracks**", such as diagnostics, energy or environment. Each team has to participate in one single track, and in the event that a project could correspond to two tracks, the iGEM recommends that the institution should split the team into two teams, giving it "*two presentations, two posters, and two chances to win most of the special prizes*" [122].

From a legal perspective, it is interesting to inquire about the issue of the **patentability of the inventions exhibited at the Giant Jamboree**. Indeed, one of the fundamental conditions of patentability is **novelty**, which implies that an invention can only be patented if it is deemed to be new. According to the World Intellectual Property Organization (**WIPO**), an invention is new "*if it is* ***not anticipated by the prior art***", which relates to "*all the knowledge that existed prior to* […] *a patent application, whether it existed by way of* ***written or oral disclosure***"[123]. The European Patent Office (**EPO**) clarifies that prior art is "*any evidence that* [an] *invention is already known*", and that "*it is enough that someone, somewhere, sometime* ***previously has described or shown or made something that contains a use of technology that is very similar to"*** **the invention**[124]. As a consequence, there is little doubt that an invention presented at the Giant Jamboree would constitute an anticipation by the prior art within the meaning of the WIPO and EPO in case of a patent request, which would most likely lead to a reject of the application.

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[122] http://2016.igem.org/Tracks, *Tracks*, the iGEM 2016 website, last accessed 25 September 2016

[123] http://www.wipo.int/edocs/pubdocs/en/intproperty/489/wipo_pub_489.pdf, *WIPO Intellectual Property Handbook*, WIPO Publication, 2004, p. 19, last accessed 25 September 2016

[124] https://www.epo.org/learning-events/materials/inventors-handbook/novelty/prior-art.html, *What is prior art?*, European Patent Office, last accessed 26 September 2016

C. The iGEM registry of Standard Biological Parts

1. The importance of Registry into the iGEM competition

Each team in iGEM competition are given a kit of biological parts and has to build biological systems and operate them in living cells. A biological part is a "sequence of DNA that encodes for a biological function"[125]. Teams modify an organism DNA in order to provide it with new properties that do not exist in nature; the application range is wide and various, from fundamental research to agribusiness.

The teams are required to create at least a new biological part or BioBrick and to submit it to the iGEM Registry in order to win a medal[126].

- For the Bronze medal, the new standard BioBrick part or Device must be **documented** and submit to the Registry under the right guidelines.
- For the Silver Medal, the new standard BioBrick or Device has to be documented and also **experimentally validated** in order to prove if it works as expected, and submitted to the iGEM Registry.
- For the Gold medal, the team must have a **functional proof of concept** of their BioBrick device (a single BioBrick is not enough).

Therefore the invention of new BioBrick and its submission in the iGEM Registry is an essential and mandatory step of the iGEM competition.

2. The philosophy of the Registry

The Registry was founded in 2003 at The Massachussets Institute of Technology, and is funded by the National Science Foundation, the Defense Advanced Research Projects Agency and the National Institutes of Health.

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[125] Registry of Standard Biological Parts, *What are biological parts* http://parts.igem.org/Help:Parts
[126] Judging/Medals, *iGEM Medals*, http://2016.igem.org/Judging/Medals

Today the iGEM Registry counts more than **20,000 documented genetic parts,** the "**world's largest open source community** collection of standard parts", opened to iGEM teams but also to academic labs and some researchers.

"The Registry is an open community that runs and grows on the "Get & Give (& Share)" philosophy"[127]

GET → Teams can **get BioBricks** from the registry and **use them** as they wish, request **physical samples**, consult **data** and previous experiences

GIVE → Teams are required to **submit their new BioBrick** and document it exhaustively

SHARE → They share their **experiences** and **collaborate**: with the wikis, meetup, skypes with other teams.

Synthetic biology offers gigantic possibilities of new properties in a wide range of application. Its progress may encounter barriers because the BioBrick do not always behave as expected. Strong communities and open science are necessary to reinforce the knowledge and to standardize the synthetic biology.

Furthermore if everyone were automatically patenting every biological part they created, it would completely paralyse research and innovation. That is why, especially in synthetic biology where the innovations are dependant from another, for instance because you can assemble existing BrioBricks to create a new one with new properties; it is important to have this kind of exchange community devoid of intellectual property rights (patents).
As an iGEM team you have access to the Registry during the year of your participation and you have to give back parts.

[127] http://parts.igem.org/Help:Philosophy

In addition academic research labs can make a request to access to the iGEM Registry. There are approximately 322 labs registered[128], it permits these labs to enter a community of Synthetic Biology or for a future or previous iGEM team to continue to have access to the Registry. If accepted by iGEM Headquarters: these labs must pay an annual subscription fee of $500 and respect the philosophy of Get, Give & Share, by giving back documentation and their biological parts. They will be part of the iGEM community (wiki platform, workshops, networking, iGEM events) and have open access to the Registry.

If you are not part of an iGEM team or lab, you can not purchase DNA distribution or part samples.

We can interrogate the supposed "open community". Within this community open access, open source and open data are ensured; nevertheless being entirely part of this community is more restricted, because it is open only to iGEM teams and academic labs.

For a more open science sort of registry there is an initiative of the BioBricks Foundation, linked to iGEM competition. They drafted the BioBrick Public Agreement (BPA)[129] in order to create a **public domain of standardized genetic encoded functions** and speed invention. It resembles to the iGEM Registry, but the main difference is that it is **open to everyone for free** if you subscribe to the agreement on the website. As a User you can access to an online database, where a research tool permits you to find the biological part you need.

3. The Registry's functioning

[128] http://igem.org/Lab_List

[129] For more information, see aforesaid in part B « The system of licenses ».

To handle the 20,000 documented genetic parts, the Registry is well organised and its spirit make the research in synthetic biology easier and faster!

The BioBrick submitted must follow strict guidelines to ensure compatibility between parts. The RFC10 **submission standard**[130], used in the Registry, forbid for instance certain restriction site or introduce silent point mutations. This recommended BioBrick assembly method make it **easier for users to assemble ancient and new parts** into more complex parts.

The teams are also required to **document each part and device** they submit, explaining how they work and how to use them. The Registry is more than a giant store of BioBricks, the progress and the **re-use are really encouraged** thanks to this documentation.

To help the teams find the adequate BioBrick, they created the **Catalog of Parts and Devices**[131] in addition to the Registry search tools. It enables the teams to browse in the registry according to many different criteria (part type, chassis, function, contributor, protein coding…).

The Registry Repository is another component of the Registry; teams can send **physical samples** of their work. And users, after a quality test of the sample, can request one and use it. This Repository goes beyond the exchange of information, making this community stronger. Thus finding the adequate "genetic lego" for your construction is way simpler.

All this functionalities make the iGEM registry highly efficient for the research and progress

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[130] http://openwetware.org/wiki/The_BioBricks_Foundation:BBFRFC10

[131] http://parts.igem.org/Catalog

III. Conciliation of aforementioned rules with the pursuit of iGEM projects in a private or open framework

A. The mindset of igem team and context

B. Pursuit of iGEM projects

1. Examples from the past

As previously discussed, a lot of team elaborate very successful projects, and invest themselves beyond the competition. Therefore, it is only logical that some teams want to pursue the project further after the competition. There have been some very successful examples of teams who have turned their iGEM project into a company after the giant jamboree in Boston. For example, the 2011 Imperial College London team turned their project into a company called LabGenius: "*a gene synthesis company, offering the world's most advanced DNA libraries. Our proprietary technology bypasses the need for long sequence hybridisation, allowing us to build high complexity libraries, beyond the capabilities of any other company* ».[132] The MIT-Entrepreneurship 2012 team developed, after the competition, a platform called Benchling : "an integrated software solution for experiment design; note-taking, and molecular biology"[133].

These examples show that it is possible to turn an iGEM project into a successful structure, but there are some legal matters that need to be taken into account before switching to another form of entity.

2. Which legal form is most suitable for iGEM startups?

[132] http://www.labgeni.us/home Accessed October 7th

[133] https://benchling.com/

Firstly, it is important to highlight that "startup" is a very commonly used word that designates a business enterprise that has been launched recently[134], but it is not a business form in the legal sense of the term. Therefore, when referring to "iGEM startups", we include a broad range of business entities such as corporations or limited liability companies.

Legislations vary a lot from a country to another, but we can highlight the most representative features of the business forms mostly chosen by iGEMers in the pursuit of their projects. Indeed, by analyzing the characteristics of iGEM teams who pursue their business, we notice that most of them choose a very similar legal status in their respective countries.

The information gathered about iGEM startups are synthetized in the table below for more clarity[135]:

Name	Country[136]	Statute	IGEM	Founded

[134] start up. (n.d.) Collins English Dictionary – Complete and Unabridged, 12th Edition 2014. (1991, 1994, 1998, 2000, 2003, 2006, 2007, 2009, 2011, 2014). Retrieved October 16 2016 from http://www.thefreedictionary.com/start+up

[135] This synthesis comes from the list of startups reported by the iGEM foundation, but it might not take into acccount the most recently incorporated or the ones that did not follow standard registration procedures. The information about these startups has been found on these websites: https://beta.companieshouse.gov.uk/company/08110518 ; https://www.linkedin.com/company/amplino ; http://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=261131503 ; https://datafox.com/bento-lab ; http://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=268871328 ; https://beta.companieshouse.gov.uk/company/09616956 ; http://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=306457664 ; http://www.bloomberg.com/Research/stocks/private/snapshot.asp?privcapId=233656324 ; http://www.datalog.co.uk/browse/detail.php/CompanyNumber/CAAB2018183729/CompanyName/FREDSENSE+TECHNOLOGIES+CORP ; http://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=265982823 ; https://beta.companieshouse.gov.uk/company/09258484 ; http://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=130407341 ; https://www.crunchbase.com/organization/hyasynth-bio#/entity ; https://beta.companieshouse.gov.uk/company/08183505 , https://www.crunchbase.com/organization/labster ; https://www.crunchbase.com/organization/morph-bioinformatics#/entity ; http://cacompany.org/co.php?id=03934899.

[136] Headquarters country

			participation	
Ambercycle	UK[137]	Inc.[138]	2013	2012 (?)
Amplino	Netherlands	?[139]	2012	2011 (?)
Benchling	US[140] (MA)	Inc.	2012	2012
Bento lab	UK	Ltd.[141]	2013	2014
Biobots	US (PA)	Inc.	2013	2014
CustoMem	UK	Ltd.	2014	2015
Eligo Bioscience	France	S.A.S[142]	2014	2014
Experiment (formerly Microryza)	US (CA)	Inc.	2010 + 2011	2010
FredSense	Canada (AL)	?	2012 + 2013	2014
Synbiota	Canada (AL)	Inc.	2010	2013
Gene Adviser	UK	Ltd.	2006	2014
Ginkgo Bioworks	US (MA)	Inc.	2004	2008
Hyasynth Bio	Canada (QC)	Inc.	2012	2014
LabGenius	UK	Ltd.	2011	2012
Labster	Denmark	?	2009	2011
Morph Bioinformatics	UK	Ltd.	2012	2013
PVP Biologics (formerly Proteus)	US (DC)	Inc.	2011	2015 (?)
SynBioBeta	US (CA)	Llc.	2006	?

137 United Kingdom
138 Incorporation
139 No reliable information was found
140 United States
141 Limited company
142 Société par actions simplifiée (equivalent to a simplified limited company)

Upcycled Aromatics	Canada (AL)	?	2012	?

From this table, we can see that half of the iGEM projects (6 of them) switched to a corporate form the year after the competition. Very few of them (only 2) did it the same year, and some teams only incorporated their business many years after. This table shows that teams, in most cases, take some extra time to finish up the final details of the project before going to business, but they do so quite quickly.

As we can see, out of the several existing forms of doing business, almost all of the United States based teams have chosen the corporation, (abbreviated Inc.) and often referred to as "corporations" and UK based teams all decided to go for the limited liability company (abbreviated Ltd.). The only French company registered under the regime of the S.A.S (société par actions simplifiée, which is the equivalent of a "simplified joint-stock company"). For clarity and understanding, here is a correspondence table between British English and American English.

	Corporation	Company
American English	company or group of people authorized to act as a single entity (they are legal persons). They can be for profit or nonprofit.	"corporation, partnership, association, joint-stock company, trust, fund, or organized group of persons, whether incorporated or not, and (in an official capacity) any receiver, trustee in bankruptcy, or similar official, or liquidating agent, for any of the foregoing[143]
British English	"A large company or group of companies	Legal entity made up of an association of persons, be they natural, legal, or a

[143] Black's Law and lee Dictionary. Second Pocket Edition. Bryan A. Garner, editor. West. 2001.

	that is controlled together as a single organization"[144]. (Abbreviated: corp.)	mixture of both, for carrying on a commercial or industrial enterprise. (Cannot include partnerships since they are not a separate legal entity).

The regime of corporations (inc.) in the United States and limited liability companies (Ltd.) in the United Kingdom are quite similar. In terms of liability, both corporations and limited companies' shareholders and directors have limited liability on the company's debts (to a certain extent), which means that their assets cannot, unless severe abuse, be seized. Then, both structures are interesting on a taxation perspective, since they are a legal entity, distinct from the one of their directors, profits cannot be subject to taxation twice.

Even though the terms can be misleading, it is important to keep in mind that both the American corporations and the English companies can be nonprofit. There is a common misconception regarding the distinction between for-profit and nonprofit. Nonprofit companies do make money, but their earnings, contrary to the ones of for profit companies are not redistributed to shareholders but must be affected to the functioning of the company. Indeed, a startup cannot function without revenue, and intellectual property is an invaluable source of income.

3. Which intellectual property assets to valorize?

In order to benefit scientific advance in the spirit of open science, we encourage teams to protect their projects by relying more on non-patent forms of protection (trademarks, design and models, and everything that falls under the scope of copyright protection). Patents can be profitable, but there are many other ways to make a company profitable, and promote open science, in the pursuit of the iGEM spirit.

[144] Cambridge dictionary online : http://dictionary.cambridge.org/dictionary/english/corporation

However, in a desire for objectivity, every possibility to protect an iGEM project is going to be developed below.

a. Patent protection

As previously mentioned, the rules of iGEM regarding patenting are quite unclear, on one hand, the foundation promotes open science when it comes to the parts deposited into the registry: "The Registry is open source, we do not take a position on IP on our parts. We don't publish any data on the state of patents and we make no claims about being able to use DNA from the Registry in commercial applications"[145].

But on the other hand, filing a provisional patent is one of the judging criteria of the "entrepreneurship track", that allows teams to be eligible for a grand prize: "The cross-track entrepreneurship prize recognizes exceptional effort to build a business case and commercialize an iGEM project (…) Have you filed a provisional patent on your project/device/process? Have you raised money to build and ship products?".

Despite this clear contradiction within the iGEM rules, that would benefit from a clarification, we are going to explain to which extent iGEM creations can be patented and how.

- **Patentability conditions**

Patentability conditions vary worldwide, therefore we are going to cover the essential rules and procedures of patenting, but one needs to keep in mind that there might be slight changes depending on the region the inventors are seeking protection. First of all, only an invention can be subject to protection. It is important to note that some teams discuss patentability without having realized an invention in the sense of patent law, and a lot of teams in the framework of the iGEM competition do have great ideas, but they do not build on them sufficiently to produce patentable material. Also, what is considered to be a patentable invention

[145] http://parts.igem.org/Help:FAQ

in a country is not going to be considered as such in another country. In a broad sense, the most libertarian ideology when it comes to patenting is found in the US law, while Europe is more conservative, and will not grant patents on new animal varieties for instance. The Canadian Biotechnology Advisory Committee made a table summing up patentable subject matter in different countries:[146]

	Canada	United States	Japan	European Union	Australia	Korea
Proteins (plant, animal, human)						
Genes (plant, animal, human)				**		
Cells (plant, animal, human)				**		
Plants						***
Plant Varieties						
Plant Breeders' Rights						
Animal Organs						
Animals						
Animal Varieties						
Human Organs						
Processes without substantial human intervention						
Animal Diagnostics*						
Animal Therapies						
Gene Therapy for Animals*						
Human Diagnostics*						
Human Therapies						
Gene Therapies for Humans*						

* Please note that the boxes "Animal Diagnostics" and "Human Diagnostics" apply only to diagnostic procedures used directly on animals or humans (that is, not diagnostic methods performed outside the body). Similarly, "Gene therapy for animals" and "Gene Therapies for Humans" apply only to gene therapy procedures performed on animal or human bodies and include neither the materials used in gene therapy nor processes that occur outside the body.
** Europe clearly stated in article 5 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions 31998L0044 Official Journal L 213, 30/07/1998 P. 0013 – 0021 that the discovery of products of the human body (including genes) were not patentable: "1. *The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable*

[146] http://www.iatp.org/files/Patenting_of_Higher_Life_Forms_and_Related_Iss.htm this table has been updated with the most recent court rulings and legislation.

inventions." But: "2. *An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."* The question of cell patentability is only evoked in recitals 16 and 38 of the directive: "(16) *Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, (...) cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented*;" "(38) *(...) the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability*".
*** Asexually reproduced plants only
Source: Gold, Richard (2001), *Patenting life forms: An International Comparison* (Ottawa: Canadian Biotechnology Advisory Committee).

This table highlights very well the difference in patentability of living organisms in Europe and in the United States, which is a crucial question in the framework of the iGEM competition. The main difference between Europe and the United States lies in the patentability of living organisms. While they both recognize the possibility to grant privative rights on such organisms, the European conception of what constitutes an invention will be much more restrictive than the American vision. For instance, in the famous Myriad Genetics case, patent protection was granted to Myriad Genetics inc. on "isolated DNA coding for a BRCA-1 polypeptide" which led the European parliament to issue a resolution against the patenting of BRCA1 and BRCA2[147].

Therefore, the protection of many iGEM projects through patent law could be easier to achieve in the United States rather than in Europe. But unfortunately, even though the majority of projects are very elaborated innovative, it is very hard to carry out a project including an invention matching patentability requirements in the short timeframe imposed by the competition, so a lot of teams do not produce patentable material anyway. But it is nevertheless possible, and we are going to go over the patentability requirements that need to be met. However, patentability conditions

[147] European Parliament Resolution on the patenting of BRCA1 and BRCA2, 04.10.2001.

vary from one state to another, so we cannot compile them into a universal list, but some conditions are found in the majority of legal systems and are therefore qualified by the World Intellectual Property Organization as "key conditions" and they are the following[148]:

- "The invention must show an element of **novelty**; that is, some new characteristic which is not known in the body of existing knowledge in its technical field. This body of existing knowledge is called "prior art".
- The invention must involve an "**inventive step**" or "**non-obvious**", which means that it could not be obviously deduced by a person having ordinary skill in the relevant technical field.
- The invention must be **capable of industrial application**, meaning that it must be capable of being used for an industrial or business purpose beyond a mere theoretical phenomenon, or be useful.
- Its subject matter must be accepted as "**patentable**" under law. In many countries, scientific theories, aesthetic creations, mathematical methods, plant or animal varieties, discoveries of natural substances, commercial methods, methods for medical treatment (as opposed to medical products) or computer programs are generally not patentable.
- The invention must be disclosed in an application in a manner sufficiently clear and complete to enable it to be **replicated** by a person with an ordinary level of skill in the relevant technical field".

- **The disclosure of the invention in iGEM participation**

If most of these conditions pose no major problem, however, in the framework of the iGEM competition, if the invention has been disclosed in any way: on the wiki,

[148] http://www.wipo.int/patents/en/faq_patents.html

during the giant jamboree or during a poster session, or by any other way, the condition of novelty will not be met in most countries. It is the case for example in all Europe, where article 54 of the European Patent Convention provides that "(*1) An invention shall be considered to be new if it does not form part of the state of the art. (2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.* "Therefore, disclosing the invention on the occasion of the iGEM competition prevents the novelty condition to be fulfilled in Europe. However, in the hypothesis that a team realizes an invention and files a patent application before disclosing anything at IGEM, the condition of novelty should still be met.

- Exceptions in some countries: the one year grace period

Although, in some countries, there is a one-year grace period during which the disclosure of the invention by its inventor does not constitute an obstacle to the novelty of the said invention. It is the case in Brazil[149] or in the United States for instance, where article 2133 Pre-AIA 35 U.S.C. 102(b) [R-07.2015] Pre-AIA 35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent : "A person shall be entitled to a patent unless (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, **more than one year** prior to the date of application for patent in the United

[149] Law No. 9,279, of May 14, 1996 article 12. « The disclosure of an invention or utility model shall not be considered to be state of the art if it occurred during the 12 (twelve) months preceding the date of filing or of priority of the patent application, if made:

I. by the inventor;
II. by the Instituto Nacional da Propriedade Industrial—INPI (National Institute of Industrial Property), by means of official publication of the patent application filed without the consent of the inventor, based on information obtained from him or as a consequence of actions taken by him; or
III. by third parties, based on information obtained directly or indirectly from the inventor or as a consequence of actions taken by him.

The INPI may require from the inventor a statement related to the disclosure, accompanied or not by proofs, under the conditions established in regulations ».

States". In total, 46 countries recognize a novelty grace period.[150] Therefore, in these countries, disclosure of the invention by its inventor less than one year before the filing of the patent will not be not be prior art to the claimed invention, so inventions disclosed in the framework of the iGEM competition should still be patentable, in these countries only, in all the other countries, the invention will be considered non novel.

- The provisional application for patent

In view of filing a patent application in the United States, there is a mechanism that can be interesting in the framework of the iGEM competition: the provisional application for patent[151] that allows the applicant to "file without a formal patent claim, oath or declaration, or any information disclosure (prior art) statement". This option is interesting when the invention is already tangible, but not yet fully developed. A provisional application is not required to have a formal patent claim or an oath or declaration. A provisional application is not examined but it provides the means to establish an early effective filing date in a later filed nonprovisional patent application filed under 35 U.S.C. §111(a) (there is a 12-month pendency period to file the nonprovisinal patent). The procedure for filing a provisional patent is quite straightforward and be obtained from the United States Patent and Trademark Office (USTPO).

However, one should be very careful about this provisional patent as it does not grant patent protection to the invention, it is only a way to delay the actual patent application. The substance of the provisional patent claims is not examined by the

[150] Struve, Frederik, "Novelty Grace Periods: A National Law Survey" (2013). Student Scholarship. Paper 3. p.1: Albania, Algeria, Andorra, Angola, Antigua & Barbuda, Argentina, Armenia, Bahrain, Belize, Bhutan, Bolivia Botswana, Brazil, Colombia, Costa Rica, Dominica, Ecuador, El Salvador, Estonia, Ethiopia, Gambia, Georgia, Ghana, Guatemala, Honduras, Iraq, Jordan, Kenya, Kyrgyzstan, Lesotho, Liberia, Mauritius, Mexico, Mozambique, Nicaragua, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Rwanda, Saint Kitts & Nevis, Tonga, Turkey, Ukraine, Uruguay.

[151] U.S. national application filed in the USPTO under 35 U.S.C. §111(b)

USTPO, it only needs to match administrative requirements. If not done correctly, the provisional patent claim can have terrible consequences, in the sense that it might only private the rightful inventor of their patenting right. As patent attorney Gene Quinn explains: "*Poorly done provisional patent applications are almost certainly useless for their intended purpose, but can be used against the inventor later as a weapon to demonstrate there was no invention, or at least that the invention had not ripened past the idea stage at the critical moment the invention was memorialized at the time of filing the provisional patent application*". Indeed, the provisional patent claim will only be reviewed at the time of the actual patent claim, in order to check if the invention was matching the requirements of 35 U.S.C. 112 at the time of the provisional patent. As said before, the filing of a provisional patent is one of the criteria used by iGEM judges to award the entrepreneurship prize. Hence, we can say that the iGEM foundation encourages the filing of provisional patents, but teams should not get involved in this process without seeking advice from a patent attorney, or they might put their intellectual property rights at risk.

Finally, one must not forget the important cost of requiring patent protection, especially because patent protection is territorial, and the invention will only be protected in the country or geographical zone where the patent has been filed. This makes the patent interesting only if the profits generated by the invention are sufficient to cover it. The World Intellectual Property Organization (WIPO) has given an estimation for these costs when filing a patent within states bound by the cooperation patent treaty:

	2 countries				7 countries				15 countries			
U.S. $	Direct	Share	PCT	Share	Direct	Share	PCT	Share	Direct	Share	PCT	Share
Official fees	6,442	38.0%	9,001	48.9%	20,067	33.8%	21,449	35.5%	36,258	30.4%	36,799	31.1%
Excluding Maintenance	5,607	33.3%	8,302	45.5%	12,960	21.8%	14,664	24.2%	21,810	18.3%	23,203	19.6%
Maintenance	835	4.9%	700	3.4%	7,108	12.0%	6,785	11.2%	14,448	12.1%	13,595	11.5%
Legal costs	4,398	25.9%	4,274	21.0%	25,836	43.5%	25,539	42.2%	61,697	51.7%	60,353	51.0%
Excluding Maintenance	4,156	24.5%	4,156	20.4%	21,616	36.4%	21,854	36.1%	50,247	42.1%	50,129	42.4%
Maintenance	242	1.4%	118	0.6%	4,220	7.1%	3,685	6.1%	11,450	9.6%	10,224	8.6%
Translation costs	6,131	36.1%	6,131	30.1%	13,494	22.7%	13,494	22.3%	21,426	17.9%	21,188	17.9%
Total	$ 16,971		$ 19,406		$ 59,397		$ 60,481		$ 119,381		$ 118,339	

Note: The patenting costs are based on estimates sourced from Global IP Estimator (http://www.globalip.com/). They include filing, examining, prosecution, granting costs and the international phase for PCT scenarios. They do not include in-house and pre-filing costs. The figures shown above are based on typical cost schedules which are indicative only; actual costs will vary widely depending on the many options that are available to applicants and the many differences in costs and fees (including legal and translation costs) around the world. The last maintenance year is 10 years from filing. See annex D for further details regarding the methodology used.

Source: WIPO

In conclusion, patenting material produced in the framework of the iGEM competition is complicated. But there are many other ways that team can value their intellectual property, and that would be more beneficial to the open science community than systematically seeking patent protection.

b. Utility models (or innovation patents or utility innovations)

They are also used to protect inventions, but are less burdensome. In some countries, utility models were referred to as "petty patents"[152]. Their main characteristics can be considered in comparison with patents. Like patents they also require a condition of novelty, but:

- they are less expensive to obtain,
- the procedure for obtaining them is shorter and simpler,
- they protect inventions that are considered to be less complex than the ones protected by a patent.
- they provide a shorter protection than patents (usually between 7 and 10 years)

[152] In Australia for instance, until 2001.

The conditions to file a utility model vary a lot from a country to another, and they are not available in every country[153]. For instance, they are not available in the United States and United Kingdom. For the aforementioned reasons, utility models are usually used for industrial inventions that have a short lifetime, or their lesser cost can be attractive to small business. They can also be used to protect incremental inventions, where the inventive step is too minor to request patent protection.

However, the interest of this mean of protection seems limited when it comes to iGEM projects. Indeed, utility models are not suitable to protect biotechnological inventions that are much too complex.

Therefore, we recommend iGEM teams who wish to create a business after the competition to rely more on the other aspects of intellectual property, and especially trademarks.

c. Trademark protection

During our research, we noticed that teams who are the most successful in the competition develop, alongside their project, a strong brand image.

This image is materialized through several items; the wiki is the main tool through which teams communicate their project to the world, and it usually bears a strong identity. Teams work a lot to build a brand image which is reflected into a visual identity, a name, a motto, a logo…

[153] Utility models (or similar/equivalent rights with a different name) are available in Albania, Angola, Argentina, ARIPO, Armenia, Aruba, Australia, Austria, Azerbaijan, Belarus, Belize, Brazil, Bolivia, Bulgaria, Chile, China (including Hong Kong and Macau), Colombia, Costa Rica, Czech Republic, Denmark, Ecuador, Estonia, Ethiopia, Finland, France, Georgia, Germany, Greece, Guatemala, Honduras, Hungary, Indonesia, Ireland, Italy, Japan, Kazakhstan, Kuwait, Kyrgyzstan, Laos, Malaysia, Mexico, OAPI, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Russian Federation, Slovakia, Spain, Taiwan, Tajikistan, Trinidad & Tobago, Turkey, Ukraine, Uruguay and Uzbekistan.

Obtaining trademark protection in most countries is usually not very difficult. The applicants need to file a request before their local trademark office (United States Patents and Trademark Office in the United States, European Union Intellectual property Office in Europe…).

- **In the European Union**

Citizens of the European can seek protection in their country first, and then extend their brand protection to the whole European union by having their local office forward the request to the European Union Intellectual Property Office (EUIPO).

The requirements for trademarks are quite easy to fulfill according to the Council's definition: "An EU trade mark may consist of any signs, in particular words, including personal names, or designs, letters, numerals, colours, the shape of goods or of the packaging of goods, or sounds, provided that such signs are capable of:

distinguishing the goods or services of one undertaking from those of other undertakings; and

being represented on the Register of European Union trade marks in a manner which enables the competent authorities and the public to determine the clear and precise subject matter of the protection afforded to its proprietor"[154].

Therefore, the regulation on the European trademark gives two positive conditions for trademark protection: the trademark must be able to distinguish the goods or the services and it must be able to be represented (the feeling of a starting engine for instance cannot receive trademark protection, because it cannot be represented). Of course, the requested sign must not be subject (or similar) to another trademark right, therefore, an anteriority search is mandatory before requiring brand protection. It is usually performed by a trademark attorney.

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[154] Regulation (EC) No 207/2009 of 26 February 2009 on the European Union trade mark

You can deposit either a word mark "just do it"[155], a figurative mark (the apple logo), a figurative mark with letters ("Coca-Cola" written in the famous font), a 3D-mark (the Toblerone bar), a color per se (Kraft foods color), a sound mark (the Metro-Goldwyn-Mayer roaring lion from the movies)[156].

Finally, the brand must be **distinctive but not descrip**tive (you cannot sell chocolate under the brand "chocolate"), and it must **not be contrary to public order** (you cannot register a brand that would offense the targeted public, for instance a brand of clothing aimed at the general public containing offensive terms).

Then, the applicants must pay a fee of 850 euros (that can be higher if the requested protection regards more than one different type of product) and wait for the approval process.

- **In the United States**

The conditions of trademark protection are quite similar to the conditions in Europe. "*A trademark is generally a word, phrase, slogan, symbol, or design, or combination thereof, that identifies the source of your goods and services and distinguishes them from the goods and services of another party*" according to the USPTO's definition.

Again, like in European law, there must be no "likelihood of confusion", which exists when the "marks of the parties are similar and the goods and services of the parties are related in such a way that consumers are likely to believe they come from the same source". Again, a "clearance search" is necessary to prevent that kind of issue.

The filling of the mark before the USTPO is also quite straightforward, the applicant must follow the procedure and pay the registration fees.

- **The international brand**

[155] EUTM 000514984

[156] Metro-Goldwyn-Mayer EUTM 005170113

The request for international brands must be submitted to the World Intellectual Property Organization by regional offices (the USTPO, a national office or the EUIPO). If the brand fulfills the conditions for the international brand (which are similar to the aforementioned conditions), it will be protected in all the countries that are parties to the WIPO treaty.
Protection of the brand is granted for a period of time that go somewhat between 7 and 10 years, and can be indefinitely renewed.

- **The display of the brand of the brand on the wiki in the framework of iGEM**

However, like we previously mentioned, "all content on this wiki is available under the Creative Commons Attribution 4.0 license (or any later version)"[157]. Even though this license only aims at protecting copyrightable material, the fact that all of the wiki is under the creative commons regime can generate embarrassing overlapping situations when it comes to brands.
Since the Creative commons licenses are irrevocable, putting your mark on the wiki, whether it is registered or not would not be a very good choice. Indeed, the Creative Commons organization itself does not recommend using a CC license on a logo or trademark because, "the special purposes of trademarks make CC licenses an unsuitable mechanism for sharing them in most cases. Generally, logos and trademarks are used to identify the origin of a product or service, or to indicate that it meets a specific standard or quality. **Allowing anyone to reuse or modify your logo or trademark as a matter of copyright could result in your inability to limit use of your logo or trademark selectively to accomplish those purposes**. Applying a CC

[157] http://2016.igem.org/Requirements/Wiki

license to your trademarks and logos could even result in a loss of your trademark rights altogether"[158].

There would be a way around it if iGEM tolerated restrictions to the creative commons license (restrictions allowed by the creative commons organization itself): "You may offer material under a Creative Commons license that includes a trademark indicating the source of the work without affecting rights in the trademark, because trademark rights are not licensed by the CC licenses. However, applying the CC license may create an implied license to use the trademark in connection with the licensed material, although not in ways that require permission under trademark law. To avoid any uncertainty, Creative Commons recommends that licensors who wish to mark material with trademarks or other branding materials give notice to licensors expressly disclaiming application of the license to those elements. This can be done in the copyright notice, but could also be noted on the website where the work is published"[159].

Therefore, if you had registered a trademark, it could possibly be excluded from the creative commons license on the wiki. However, we do not know if this restriction, even though tolerated by the creative commons organization would be in compliance with iGEM rules.

In our opinion, allowing teams to protect the brand they have developed during the competition time would not have a negative impact on the competition's functioning, and on the open science approach. Indeed, teams have provided a

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[158] https://creativecommons.org/faq/#can-i-offer-material-under-a-cc-license-that-has-my-trademark-on-it-without-also-licensing-or-affecting-rights-in-the-trademark

[159] The Creative Commons organization provides a disclaimer example: "The text of and illustrations in this document are licensed by [*brand name*] under a Creative Commons 4.0 Attribution license. [*brand names, slogans, words subject to protection*] are trademarks of [*brand name (Inc.)*], registered in the [*registration State*] and other countries.

substantial amount of work in order to come up with a brand, and allowing anyone else to reuse it would not help science and open innovation in any way because the purpose of brands is precisely reserve rights in order to identify products coming from a specific origin. On the opposite, in case of (mis)use of that brand by a third party, it would be damageable to the team who originally created it, because in the public's opinion, the products and services bearing the distinctive signs are associated to that sign, and to the team who invented it.

If our goal is to promote open science and innovation, we should provide the actors of this evolution (the scientists willing to take their project beyond the competition) with the necessary tools to protect their image, namely, brand protection. This is a minimum requirement for the development of a business after the competition, because a lot of teams have put a lot of effort in the research of their name, that they use as a brand in practice.

Third parties will not be prejudiced by the fact that they cannot reuse the brand of a previous team, because this name will not identify their products, and worse, could generate a confusion in the public's mind between the products or services developed by different parties.

C - Propositions for a better practice of open science in the framework of the iGEM competition, and outside of it

1°) Suggestions to the iGEM Foundation

a) Further promoting the pursuit of iGEM projects in an open science framework

Running an open science research project is complex due to questions of funding. As underlined by Edwin Dalmaijer, research fellow at the Oxford Cognitive Neuropsychology Centre (OCNC), in the current scientific environment, a core part of the job is publishing papers. Therefore, by distracting oneself from publishing and by opening their work to the broadest public, one might put oneself out of a job in the long run, "*because research positions are offered to those who publish a lot*"[160].

Consequently, because the iGEM Foundation is a major player in the field of synthetic biology, and because it is dedicated to "*education and competition, advancement of synthetic biology, and the development of open community and collaboration*"[161], we believe that it should devote some of its considerable resources to the benefit of a few selected iGEM competitors that would wish to carry on with their project in an open model. Such assistance could take various forms, such as providing the rewarded teams with a lab for a specified period, offering them a start-up grant, or simply giving them technical assistance and help with their research work. In doing so, the iGEM competition would elevate to become a huge springboard in the open science world.

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[160] http://www.pygaze.org/2016/03/the-downsides-of-open-science-that-nobody-talks-about/, E. Dalmaijer, *The Downsides of Open Science that nobody talks about*, PyGaze, 18 March 2016, last accessed on 16 October 2016

[161] http://igem.org/About, *About*, the iGEM website, last accessed on 16 October 2016

b) *Clarifying the Intellectual Property issues within the iGEM competition*

As participants in the iGEM, and as intellectual property law students, we found that questions relating to intangible rights in the framework of the competition were not properly explained to the teams. Indeed, as shown above, by putting the details of their scientific project on a publicly accessible wiki, and by presenting it at the Giant Jamboree in front of an audience composed of scientists and enthusiast from all backgrounds (iGEM teams, academic or nonprofit researchers, industry or corporate representatives, *etc.*[162]), the iGEM teams bring their inventions in the public domain. In effect, by sufficiently disclosing their inventions, the competitors take away the novelty of said inventions by creating prior art, which makes them unpatentable.

Similarly, although one of the aims of the Registry of Standard Biological Parts is to develop an "*open community of biological engineers and scientists*"[163], it is made clear that iGEM does not take position on IP on their parts. What this goes to say is that said parts can be patented, and that the users of the Registry have therefore no guarantee that they can use DNA taken from the Registry in commercial applications[164].

With this in mind, we suggest that sufficient advance warning should be given to the iGEMers on what exclusive rights they are giving up by exposing their inventions without taking appropriate actions to reserve them beforehand. Also, we recommend that, contrary to what iGEM currently does[165], a minimum of information is published on the state of patents in the Registry, so that contributors of this huge

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[162] http://2016.igem.org/Giant_Jamboree/Register, *Register*, the iGEM 2016 website, last accessed on 16 October 2016

[163] http://parts.igem.org/Help:About_the_Registry, *Help: About the Registry*, the Registry of Standard Biological Parts, last accessed on 16 October 2016

[164] http://parts.igem.org/Help:FAQ, *Help:FAQ*, the Registry of Standard Biological Parts, last accessed on 16 October 2016

[165] Ibid.

collection of DNA parts may freely develop innovative commercial uses without being troubled by possible patent holders.

c) *Adding a confidentiality clause into the signup agreement*

An interesting proposal was submitted by the 2014 University of Oxford iGEM team in the Intellectual Property report they wrote for the competition[166]. Their idea was to insert a "confidentiality clause" into the iGEM signup agreement, "*so that the jamboree is no longer in the public domain*", offering teams the "*discretion to apply for a patent for a limited period following the jamboree*".

Although retaining the possibility for the teams to patent their inventions appears to be contradicting the open science philosophy that was exposed in this report, it should be pointed out that in practice, the risk with inventors encountering difficulties in patenting their creations is that they might end up protecting their work with a trade secret. As outlined by the Oxford team, the latter approach is ultimately "*more detrimental to open source ideals than is patent*". Indeed, society has a huge interest in patents, which is that exclusive rights are granted to a patentee for a limited period of time in exchange of a description of their invention that must provide sufficient detail for a person skilled in the art to be able to make and use said invention[167]. In the case of a trade secret, no registration is required, and the secret is kept for as long as the invention is not publicly disclosed, which may never happen.

Therefore, while patents are often regarded as being detrimental to free innovation and competition because they grant their holder with a monopoly on an invention,

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166 http://2014.igem.org/wiki/images/8/86/IP_REPORTWEBVER.pdf, *Intellectual Property REPORT*, University of Oxford iGEM Team, 2014, last accessed on 16 October 2016

167 https://www.uspto.gov/web/offices/pac/mpep/s2164.html, *Manual of Patent Examining Procedure*, Chapter 2100, Section 2164, Ninth Edition, Revision 07.2015, Last Revisited November 2015, last accessed on 16 October 2016

this vision is at least partially biased, first because every patent application includes a compulsory description of the object of the protection, which is publicly accessible, and second because the exclusive rights of a patentee are only temporary.

Finally, as set out further, patents are not inconsistent with the idea of an open science commons, of which they would even serve as a basis.

d) Giving the teams more freedom over what license they want for their wiki space

As already explained, publications on the iGEM wiki are covered by the Attribution 4.0 license, the most open and permissive license proposed by the Creative Commons organization. All the content hosted on the wiki can therefore be freely shared and adapted in any way, even commercially. The only obligations of the content user are to give attribution for what they took, and, when appropriate, to indicate if changes were made.

Observing that teams currently don't get to customize the Creative Commons license (CC) used for their wiki space, we suggest that iGEM give them this possibility. In effect, we believe that ultimately, allowing teams to opt for a less open form of Creative Commons license is never more than just letting them put their wiki content under a "less open" license, but an open source license nonetheless. In sum, the most restrictive CC license will always be more permissive than traditional copyright.

Moreover, we assert that giving this choice to iGEM teams would not conflict with an open science spirit, for the sheer fact that in the vast majority of cases, CC licenses simply don't concern scientific contents. Indeed, as explained before, CC licenses

are built upon copyright, which relates back to original works of authorship[168] (literary and musical works, drawings, pictures, movies, source code of a computer software, *etc.*), as opposed to industrial property, whose protection takes various forms, namely patents, industrial designs or trademarks. Arti K. Rai and James Boyle, Professors at the Duke Law Center for Innovation Policy, explain that in the case of iGEM, although some may argue that the strings of DNA bases described by teams on their wiki are comparable to source code (which is covered by copyright), "*the ability to invoke copyright is by no means clear*", adding that "*an obvious alternative is patents*"[169].

At the presentation he gave during the iGEM Île de France meetup at the Institut Pasteur on 6 August 2016, Jonathan Keller, lawyer and general secretary at La Paillasse (a Parisian community lab for civilian biotechnologies[170]) explained to an audience of iGEMers that a good way to overcome the financial challenges of leading an open science research would be to refrain from registering patents, while trying to make a profit from the other intellectual property rights in relation to the project (copyright, trademarks, industrial designs, *etc.*). We believe Mr. Keller's idea is very much in line with our suggestion of giving flexibility to the current licensing system of the iGEM wiki, as it would make it possible for teams to forbid the circulation of derivate works based on their creations, or, most importantly, prevent any commercial use of their works.

168 http://www.copyright.gov/help/faq/faq-protect.html, *What Does Copyright Protect?*, copyright.gov, the United States Copyright Office, last accessed on 16 October 2016

169 http://journals.plos.org/plosbiology/article?id=10.1371%2Fjournal.pbio.0050058, Rai A, Boyle J, *Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons*, PLoS Biol 5(3): e58, doi:10.1371/journal.pbio.0050058, 13 March 2007, last accessed on 16 October 2016

170 http://lapaillasse.org/places/la-paillasse-paris/, *La Paillasse à Paris*, La Paillasse, last accessed on 16 October 2016

2°) Suggestions to the open science decision makers

a) Support and strengthen the institutional initiatives in favor of open science

Aside from the scientific community, public authorities also have a crucial role to play in the development of openness in the scientific research. According to Noëmie Rosemberg, librarian at the French Bibliothèque Universitaire des Langues et Civlisations (BULAC), three types of tools must be envisaged to foster the development of open science:

- The mandates (the "sticks"):
  - ➢ The EU's Horizon 2020, which was already mentioned, provides that all projects receiving funding from the Programme will have the obligation to make sure any peer-reviewed journal article which they publish is openly accessible, free of charge[171];
  - ➢ The University of Liège (ULg) implemented an institutional policy for mandatory repositories[172];
  - ➢ The Irish Government adopted the "National Principles for Open Access Policy Statement", whereby the outputs from publicly-funded research are made "*publicly available to researchers, but also to potential users in education, business, charitable and public sectors, and to the general public*"[173].
- The incentive mechanisms (the "carrots"):

171 https://www.iprhelpdesk.eu/Fact-Sheet-Open-Access-to-Publications-and-Data-in-H2020-FAQ, *Open Access to scientific publications and research data in Horizon 2020: Frequently Asked Questions (FAQs)*, the European IPR Helpdesk, last accessed on 16 October 2016

172 https://orbi.ulg.ac.be/project?locale=en&id=03, *Open Access at the ULg*, Open Repository And Bibliography, University of Liège, last accessed on 16 October 2016

173 http://www.iua.ie/wp-content/uploads/2012/10/National-Principles-on-Open-Access-Policy-Statement-FINAL-23-Oct-2012-v1-3.pdf, *National Principles for Open Access Policy Statement*, 23 October 2012, last accessed on 16 October 2016

- The Horizon 2020 Programme involves that under certain conditions, costs related to open access to research data are eligible for reimbursement for the duration of the project[174].

- The infrastructures and strategies enabling the development and promotion of open science:
  - The French Centre pour la Communication Scientifique Directe (CCSD)[175] developed an open archive platform called "HAL" dedicated to the filing and dissemination of academic or industrial research papers and theses[176];
  - The US called upon the scientific agencies of the federal Government in 2013 to develop programs aiming at enhancing and facilitating the access to federally funded research.

But as outlined by Ms. Rosemberg, at the governmental level, the fight for open science is mainly waged on the ground of intellectual property, namely because most legislations do not facilitate the free sharing and reuse of protected contents. In some countries, things seem nevertheless to be changing, like, for instance, in Germany, where the copyright law was modified in 2013 to allow publicly funded researchers to openly disseminate their results even if they had assigned the exploitation rights beforehand (after having respected a twelve-month embargo)[177].

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[174] http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf, *H2020 Programme, Guidelines on FAIR Data Management in Horizon 2020*, European Commission Directorate-General for Research & Innovation, Version 3.0, 26 July 2016, last accessed on 16 October 2016

[175] https://www.ccsd.cnrs.fr/fr/ccsd-centre-pour-la-communication-scientifique-directe/, the CCSD website, last accessed on 17 October 2016

[176] https://hal.archives-ouvertes.fr/, the HAL website, last accessed on 17 October 2016

[177] https://bulac.hypotheses.org/3362?lang=fr_FR, Noëmie Rosemberg, *Open Science, où en est-on ? #OAWeek*, Actualités BULAC, 12 October 2015, last accessed on 17 October 2016

b) *Towards an open science commons?*

At the current time, there is no specific widespread framework for openly sharing scientific methods, results and inventions. What the parties in the field of science mostly use are open source licenses applied to scientific research, which were originally designed to allow software producers making their source code available for everyone. Therefore, these "commons" licenses are not always the most appropriate instrument for scientific purposes, namely because, as explained above, they rely on copyright while most scientific contents are protected by patents.

This does not however mean that no patent-based commons currently exist. Indeed, as Professors Rai and Boyle recall, the Biological Innovation for an Open Society (BIOS)[178] has actually built its own license and uses patent protection on a few key plant gene transfer technologies to force licensees to put improvements to those technologies in the commons[179]. But what works for a limited number of very specific technologies with the BIOS may not be an option for projects like the Registry of Standard Biological Parts, which comprises "over 20,000 documented parts"[180]. In effect, as stressed by A. Rai and J. Boyle, a challenge which will have to be somehow overcome is expense, as patenting a single part can cost tens of thousands of dollars[181].

While A. Rai and J. Boyle also hint at the possibility to use "broad patents", which are foundational patents whose scope is described in such a way that they cover an unduly big part of a technical field, in parallel, they point out the fact that, first,

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[178] http://www.bios.net/daisy/PELicense/751, *The CAMBIA BiOS License for Plant Enabling Technology*, Biological Innovation for an Open Society, 2007, last accessed on 17 October 2016
[179] Rai A, Boyle J, op. cit.
[180] http://parts.igem.org/Main_Page, the Registry of Standard Biological Parts, last accessed on 17 October 2016
[181] http://www.ipwatchdog.com/2015/04/04/the-cost-of-obtaining-a-patent-in-the-us/id=56485/, Gene Quinn, *The Cost of Obtaining a Patent in the US*, IP Watchdog, 4 April 2015, last accessed on 17 October 2016

doing so would mean that the registry "*would essentially be exploiting flaws in the current patent system for commons-expanding purposes*", and second, that it would require to identify an area of inventive territory that is quite broad but nonetheless not suggested either by prior broad patents, or by information already in the public domain[182].

c) An alternative solution with the use of non-assertion statements?

Another possibility evoked by Professors Rai and Boyle is the use of statements of non-assertion, whereby patents owners contributing to an open science repository would promise not to assert any of their intellectual property rights against users of said repository. Such statements have already been made by important technology companies, such as IBM[183] or Sun Microsystems about some of their patents, to ensure that users working on open source software could freely do so. In the framework of synthetic biology, where most patents are held by academic and governments institutions these statements are a real possibility[184].

However, the problem with non-assertion statements is that they do not provide the owner of an open science repository with a secured proprietary right, which, according to A. Rai and J. Boyle, they would only gain if they had a license with explicit permission to sublicense[185].

d) The possibility of a contract or "clickwrap" license?

Upon entering the database of the BioBricks Foundation, users and contributors have to sign the "BPA contract", by which a person called the "Contributor" "*makes an irrevocable promise not to assert any existing or future intellectual property rights*

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[182] Rai A, Boyle J, op. cit.
[183] http://www.ibm.com/ibm/licensing/patents/pledgedpatents.pdf, *IBM Statement of Non-Assertion of Named Patents Against OSS*, 1st November 2005, last accessed 17 October 2016
[184] Rai A, Boyle J, op. cit.
[185] Ibid.

over something against the other party to the contract (the "User"). The User in turn promises a few simple things, such as to provide attribution to the Contributor, where requested, and to respect biological safety practices and applicable laws"[186].

The BPA contract is an illustrative example of "clickwrap" license, a form of contract between users and contributors of an open database which could be used as a way to secure and expand an open science ecosystem, particularly since, unlike formal commons systems, it has the advantage of not requiring any underlying property right.

However, one major flaw of clickwrap licenses is that they only bind the parties to the agreement, meaning that in order for the system to remain reliable for users, leakage needs to be carefully avoided and prevented. The most obvious way to deal with this risk is to put strict restrictions on information dissemination, which runs counter to the open science philosophy by preventing simple and conventional data publication. The HapMap international database of human genetic variation[187], for instance, used to prohibit the dissemination of its open data to anyone who had not signed on to the license[188].

e) An opportunity for a sui generis right for open science contents?

A *sui generis* right is a derogatory legal regime created to specifically frame a particular juridical question. The EU already has sui generis protection for databases, which is distinct from copyright or industrial property law.

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[186] https://biobricks.org/bpa/faq/, *Frequently Asked Questions*, BioBricks Fondation, last accessed on 18 October 2016

[187] https://www.ncbi.nlm.nih.gov/probe/docs/projhapmap/, *HapMap*, National Center for Biotechnology Information (NCBI), last accessed on 18 October 2016

[188] Rai A, Boyle J, op. cit.

In 2005, the Knowledge Ecology International organization (which was then called Consumer Project on Technology) drafted a "*Treaty on Access to Knowledge*", in which they proposed to establish a new *sui generis* right for "*Knowledge Commons Databases*", which would be protected from patents on a certain type of improvements for a specified period of time[189].

Another interesting *sui generis* perspective, which was mentioned to us by Jonathan Keller, is the one of an "open patent", what commentators affiliated with the Access to Knowledge proposal refer to as "social patent". The idea would be to create a new type of patent which would be significantly less expensive to secure than the traditional one, and would not grant its owner with a commercial exclusivity. In sum, the social patent would be used as a bulwark to prevent the reservation of high value scientific innovations by big firms to the detriment of the global scientific community. We believe this proposition is relevant, because what some open science supporters currently do is systematically filing regular patents for their inventions to prevent firms from doing so, which is both wasteful and counterproductive, especially for smaller structures.

In any event, as stressed by Professors Rai and Boyle, introducing a new legislation is a "*difficult, uncertain, and slow route*"[190].

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[189] http://www.cptech.org/a2k/a2k_treaty_may9.pdf, *Treaty On Access to Knowledge*, Consumer Project on Technology, draft 9 May 2005, article 5-6, last accessed on 18 October 2016
[190] Rai A, Boyle J, op. cit.

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